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Appropriate Perspectives for Health Care Decisions

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Introduction

NICE uses cost-effectiveness analysis to compare the health benefits expected to be gained by using a technology with the health that is likely to be forgone due to additional costs falling on the health care budget and displacing other activities that improve health. This approach to informing decisions will be appropriate if the social objective is to improve health, the measure of health is adequate and the budget for health care can reasonably be regarded as fixed. If NICE were to recommend a broader 'societal perspective', wider effects impacting on other areas of the public sector and the wider economy would be formally incorporated into analyses and decisions. The problem for policy is that, in the face of budgets legitimately set by government, it is not clear how or whether a societal perspective can be implemented, particularly if transfers between sectors are not possible. It poses the question of how the trade-offs between health, consumption and other social arguments, as well as the valuation of market and non market activities, ought to be undertaken.

Aims and objectives

The overall aim of the project is to develop a conceptual framework to assess the implications of alternative perspectives, and to undertake a series of case studies to inform the decisions about the appropriate perspective for NICE Technology Appraisal. The project has the following objectives:

(i) To undertake a review of UK policy and of policies adopted elsewhere and to summarise key literature relating to the choice of perspective.
(ii) To develop a formal conceptual framework to distinguish questions of value and fact and assess the performance and likely implications of alternative policies.
(iii) To undertake a series of selected case studies to quantify important non-NHS costs and to illuminate different ways of incorporating these into economic analysis to inform NICE decisions.
(iv) To identify the key issues to be borne in mind when considering the possible policy responses to the problem of appropriate perspective.

Focussed literature review

A review of current UK policy and of policies adopted elsewhere reveals considerable variation in the type of perspective claimed, a lack of clarity on what constitutes a broad societal perspective and little or no consideration of the impact of fixed budgets. The justification for the type of policies adopted is also somewhat limited, commonly resting on literature which ignores the implications of fixed budget constraints. This lack of clarity and ambiguous terminology is also reflected in the published cost-effectiveness literature, with many studies claiming to take a societal perspective when in fact their analysis is restricted to the health care system.

A conceptual framework

There is a spectrum of current policies ranging from ignoring the fact of fixed budgets to acknowledging budget constraints but ignoring the effects external to the health care system. Three alternative policies are characterised and examined:

A. *Ignore the wider costs outside the health sector*. This represents NICE technology appraisal policy following revision of its methods guide in 2008.
B. *Treat any wider costs as if they fall on the budget constraint*. This represents a rather naive view that all costs should be included but decisions should still be based on comparing the resulting incremental cost-effectiveness ratio (ICER) with a cost-effectiveness threshold reflecting opportunity costs to that budget.
C. *Ignore the budget constraint*. This represents the greater part of the literature on evaluation outside health (cost-benefit analysis), where the fact of fixed budget constraints and the implications for opportunity costs are rarely acknowledged and even less commonly dealt with analytically.

General framework

A general framework would allow a comparison of the net health gained in the health sector with the health equivalent of the net consumption costs or benefits falling on the wider economy. This is equivalent to giving some weight, between zero and one (based on the ratio of the cost-effectiveness threshold to the consumption value of health), to any net consumption costs or benefits, and effectively places policy between the two extremes of policies A and C above. This could be considered equivalent to NICE's pre-2008 position of taking external costs 'into account'. How do the three policies outlined above compare against this general approach to reflecting non-NHS costs?

Marginal changes

We distinguish two situations regarding the impact of new technologies on the NHS: marginal and non marginal changes. When changes are marginal, the impact on the NHS budget is small and only the least valuable existing health care is displaced (the cost-effectiveness threshold does not change). In this situation, each of the three simple decision rules creates biases in different directions depending on particular circumstances. No single rule is unequivocally superior and, in each case, the bias could lead to false positive decisions, where a technology that should be rejected is wrongly approved, or false negative decisions where a technology that should be approved is wrongly rejected (see Table III, Section 2.2).

Non marginal changes

Since the additional health care costs of new technologies tend to be positive, the repeated application of the decision rules to a sequence of decisions will ultimately have non marginal effects: increasingly valuable health care will tend to be displaced (the cost-effectiveness threshold will tend to fall). This poses a number of problems:

- A failure to account for non marginal effects will lead to biased assessments of cost-effectiveness. This will favour new technologies resulting in unambiguous increases in false positive decisions.
- Even if these effects could be accounted for and bias avoided, unless transfers are made to compensate the NHS then the implied reallocation of resource between sectors may not be socially desirable.
- The informational requirements to fully account for non marginal effects cannot generally be achieved so this cannot represent a realistic or feasible policy option.
- In these circumstances one policy option is to give some weight to net consumption costs or benefits but to ignore possible non marginal effects. This will always have a positive basis in favour of new technologies which will be greater when non marginal effects are believed to be large relative to the external effects. When non marginal effects are believed to be significant a combination of ignoring any net consumption benefits (Policy A) but treating any net consumption costs as if they fall on the NHS budget (Policy B), might mitigate this problem; the negative bias in each case tending to offset the positive.

Transfers between sectors

Without the possibility of transfers between sectors, which would internalise costs and benefits external to the health system, a technology which is not cost-effective from the perspective of the health care system may be rejected despite offering significant benefits to other public and private sectors. In principle, the transfers or compensation required between budget-constrained sectors (e.g. between the NHS and criminal justice) can be identified. However, such transfers might not be regarded as a feasible policy option because they may be costly to implement and also might be considered undesirable, as responsibility for public expenditure and its allocation would be partly transferred to those bodies which make decisions about health technologies.

Illustrative examples

Four case studies based on past NICE appraisals demonstrate that whether a technology tends to offer external benefits or impose costs will depend on the nature of the technology (e.g. whether it primarily affects mortality or quality of life), the type of disease (e.g. acute or chronic) and the type of

patient population (e.g. age, gender and employment status). In general, the case studies suggest that there tend to be net consumption benefits to the wider economy associated with effective health care. It also indicates that this depends critically on the age of the populations, with reduced mortality in older populations associated with net consumption costs. The sources of evidence available to estimate net consumption effects retrospectively were limited in a number of important respects, so the results can only be regarded as indicative and illustrative. The analysis indicates that some key questions of how to value productivity and the financial consequences for patients would need to be resolved. Robust estimates would require additional analyses as an integral part of the NICE appraisal process. Clear guidance on how this ought to be done would be required to allow a consistent approach across economic evaluations. Any guidance would need to be sufficiently robust to make inappropriate estimates detectable and the process of evidence review would be need to be sufficiently rigorous to detect false or biased claims.

Implications for policy

The question of what is the appropriate perspective for decisions made by NICE is not simply a technical one. It also poses fundamental questions about social value and the role that economic analysis ought to play in social choice.

Questions of value

Taking account of effects outside the health care sector requires some means of valuing health gained and forgone within the health sector relative to costs and benefits falling on the wider economy. The rate at which society is willing to trade social arguments including health and consumption is commonly described as a 'social welfare function'. A key question is whether it is possible or desirable to specify such a description of all possible social states which will have implications for decision across all sectors, not just health. If a complete specification of all social arguments is not possible or if any particular welfare function does not carry a broad consensus or obvious legitimacy, then attempts to formalise and codify these trade-offs might be undesirable because the prescriptions may well conflict with other objectives of social policy and lead to undesirable and socially divisive changes to the health care system. For example, this may be particularly acute when wider considerations inevitably lead some technologies, which NICE considers cost-effective from a NHS perspective, to be rejected. These will tend to be technologies in older populations or which offer life extension in chronic diseases where a return to productive activity is not possible. Nevertheless, the trade-offs still need to be made but a more deliberative rather than prescriptive approach might be regarded as more appropriate.

Questions of fact

Extending the NICE perspective beyond the NHS poses a series of empirical questions which would need to be resolved:

- An estimate of the cost-effectiveness threshold is required as well as some assessment of the possible impact of non marginal impacts on the NHS.
- An agreed estimate of the consumption value of health (the amount of consumption individuals are willing to give up to improve their own health) is needed.
- If transfers between sectors are to be considered then some assessment of relevant thresholds in other budget-constrained sectors would be required.
- Robust estimates of the cost of care not borne by the NHS, and the external effects on the wider economy would be needed. There are further difficulties in establishing how these elements should be measured and valued.

Displaced consumption effects

The additional health care costs of new technologies will displace other health care activities, not only resulting in forgone health elsewhere, but also forgone benefits to patients' carers and the wider economy. Therefore, it is not sufficient to observe net consumption benefits associated with a *new technology* but that these exceed the consumption benefits which maybe forgone elsewhere as other NHS activities are displaced. Extending the current NICE perspective is likely to provide an incentive for manufactures to search assiduously for evidence of external benefits associated with new

technologies, but offer little incentive to identify those external benefits which may be forgone. This could result in a bias in favour of new technologies and a danger that more consumption benefit will be forgone than gained.

Retaining NICE's NHS perspective may more appropriately respect the overall consumption effects of new and displaced technologies. Those technologies which generate a net health improvement can also be expected to result in an overall net consumption benefits (e.g. early return to usual activities, less carer burden), because improvements in health are in general associated with wider economic benefits. Therefore, those technologies which would already be regarded as cost-effective from an NHS perspective by offering net health benefits to the NHS are likely also to provide overall net consumption benefits as well. Equally, those technologies not currently regarded as cost-effective from an NHS perspective would, if approved, reduce health benefits across the NHS and tend to impose overall consumption costs. Nevertheless, there will be exceptions, where the net consumption benefits associated with the health gained is expected to be substantially greater or less then other displaced NHS activities. Therefore, some assessment of the net consumption benefits likely to be displaced is necessary even if there is more selective consideration of wider effects. However, such assessment remains a considerable challenge even if investments which include external effects are compared to the specific disinvestments required.

Dynamic effects

Current NICE technology appraisal process, in common with other policies based on cost-effectiveness analysis, offers manufacturers the opportunity to price their technology to the point where the net health benefits to the NHS are zero (i.e. where the ICER equals the cost-effectiveness threshold). Extending the NICE perspective to take more formal account of any net consumption benefits will provide an incentive to price technologies to the point at which the overall net benefits, including any benefits to the wider economy, will be zero. Therefore, any benefits to the wider economy will tend to be appropriated by the manufacturer through higher prices, at least during the period of patent protection, turning what were external benefits into higher internal NHS costs. Without transfers from beneficiaries in the wider economy or a compensating increase in the budget for health care through general taxation, an increasing proportion of the NHS budget will be devoted to payment of rent for benefits which fall outside health, and a smaller proportion will be available to offer health care which improves health outcomes. In the longer run, these incentives will tend to influence investment and development decisions so that the type of technologies available will be licensed in diseases and patient groups which are more likely to demonstrate external benefits and command higher prices.

Considerations

The following key considerations need to be borne in mind when assessing the possible policy responses to the problem of appropriate perspective.

- Whether a formalisation and prescription of the necessary trade-offs, based on a particular social welfare function, is desirable and sustainable.
- The importance of accounting for the likely non marginal effects of individual decisions or a series of decisions.
- Whether transfers between sectors are regarded a feasible policy option.
- The importance of making a proper assessment of any wider consumption benefits which may be forgone.
- The likely dynamic effects of more formally taking account of external consumption benefits.
- Potential conflicts with other objectives of social policy and widely accepted social value judgements.
- The difficulty of resolving questions about how best to measure and value external effects.
- The additional costs that the assessments required would place on NICE appraisal process.

Conclusions

It is possible simply to ignore the NHS budget constraint in NICE decision-making. However, this fails to acknowledge or deal analytically with the salient feature of a collectively funded health care system: resources are allocated by government so that the budget must properly be regarded as fixed by a

body like NICE. There are good reasons why the cost-effectiveness threshold for the NHS will differ from how much of their own consumption individuals are willing to give up to improve their own health. Therefore, even for marginal changes, ignoring the fact of fixed NHS budgets has little to commend it.

After 2008, NICE policy restricted perspective to that of the health care system in most circumstances. Initially this policy appears difficult to justify. However, in the light of further examination of the other considerations including the difficulty of robust measurement and the additional costs of appraisal, the potential biases associated with other feasible policies as well as their likely dynamic effects and the challenge of accounting for any wider benefits which may be displaced by positive NICE guidance it may well be a reasonable and sustainable response to this policy problem. Although, in general the health care system perspective is likely to be sufficient, there will be exceptions: where the external benefits associated with the health gains are likely to be substantially greater or substantially less than the external benefits associated with health forgone elsewhere in the NHS. Current policy does allow consideration of limited external effects in exceptional circumstances, identified by the Department of Health before referral of the topic to NICE. If the criteria for exceptional circumstances were based on an assessment of whether the external benefits are likely to be substantially greater or substantially less than existing NHS activities this would signal to NICE when they might be considered as part of the Appraisal Committee's deliberations. It should be noted, however, that as well as identifying exceptions which are likely to offer overall net external benefits it will also be necessary to identify exceptions which are likely to impose overall net consumption costs.

Between 2004 and 2008, NICE methods guidance suggested that a non-reference case analysis which included wider costs would be taken into account in the Appraisal Committee's deliberative process. This policy could be interpreted as an implicit recognition of the more general approach to marginal changes where wider effects are given some but not full weight. Any return to this previous NICE policy would need to make the basis of any deliberation more explicit, including guidance on measurement and valuation of wider effects, an indication of the weight that might be attached, and how this assessment might be modified by consideration of non marginal effects and potential conflicts with other objectives of social policy. If these deliberations are made more transparent and predictable then the type of dynamic effects on prices and NHS costs discussed above may be expected to emerge.

The critical question, however, of what wider benefits are likely to be forgone as a consequence of positive NICE guidance would remain unresolved. It should be recognised that extending the perspective for all technologies appraised by NICE would impose additional costs on the appraisal process and introduce the possibility of a biased assessment if the consumption benefits which might be forgone are more difficult to identify. The problem may be more manageable if the consideration of wider effects was restricted to those exceptional cases where a health care system perspective is more likely to be inadequate, i.e., where the external benefits are likely to be substantially greater or less than current NHS activities which may be displaced and where the impact of approval is likely to be marginal. This more focused deliberative approach would require explicit criteria for when an exceptional case could be made, possibly based on the nature of the technology, the type of disease and the patient population. Nevertheless, the repeated application of this policy will lead to non marginal changes and a positive bias in favour of new technologies. In combination with more restrictive policies (i.e. to ignore external benefits but treat any wider costs as if they fall on the NHS budget), the effect of non marginal impacts might be mitigated. However, without some empirically based assessment of non marginal impact, such a combination of policies may be open to challenge.

Keywords:
Perspective. Cost-effectiveness analysis. Economic evaluation.

1. Introduction

Decisions based on cost-effectiveness analysis compare the health benefits expected to be gained by using a technology with the health that is likely to be forgone due to additional costs falling on the health care budget and displacing other activities that improve health. This approach to making decisions in health care will be complete and reasonable if the objective of collectively funded health care is to improve health across the health care system; that the measure of health gained and forgone captures enough aspects of health and other aspects of social value to be useful; and that the budget for health care ought to be regarded as fixed by the decision making body.

However, this approach also relies on the assumption that there are no effects outside the health care sector, or any effects are small or not socially valuable compared to the effects within the health sector. These effects fall into two broad types: i) direct costs of care that do not fall on the health care budget and ii) the indirect external effects on the rest of the economy.

Some of the direct costs of care are borne by patients, such as out of pocket costs as well as their time in accessing care. It may also include the direct financial consequences of ill health (and earlier recovery) for patients and families if these are not fully captured in measures of health related quality of life. It will also include the time and resources devoted to caring for patients outside the health care system. These costs may be direct costs to the patient if formal (marketed) care is purchased. More often informal (non marketed) care is provided but the opportunity cost of this activity (what society loses) still needs to be valued. Although, direct costs may fall on marketed and non marketed activities (e.g., time and informal care) they can in principle be valued in terms of the equivalent consumption forgone, i.e., expressed as a consumption cost for the wider economy. An effective health technology may reduce these costs (e.g., a quicker recovery) or increase them (e.g., prolong survival in a chronic state).

The indirect external effect on the wider economy also needs to be valued. These are effects external to the patients, their family or informal carers but are valued by the rest of society. For example, returning a patient to active participation in the labour market will in many circumstances add to production in the economy. This will be a net benefit to society if the value of the additional production exceeds the individual's additional consumption over their remaining life expectancy. There has been much debate about whether changes in production are maintained in the long run or only have short term effects.[1] However, which ever view is taken the external effects for the rest of society must value any additional production net of consumption. Therefore, an effective health technology may provide external benefits by reducing mortality in economically active groups whose production is likely to exceed their consumption. However, it may also impose external costs on the economy if it reduces mortality in populations where remaining life cycle consumption exceeds the value of production (e.g., older populations).[2]

All these direct and indirect external effects can be expressed in a common numeraire of consumption gains and losses. The overall effect can be expressed as a net consumption cost, which if positive indicates net consumption losses to the wider economy and if negative indicates net consumption benefits.

The problem for policy is that, in the face of budgets set by a socially legitimate higher authority (government), it is not clear how or whether a broader social perspective, which would include all these effects on all sectors, should be implemented – particularly if transfers between sectors are not regarded as a feasible policy. There is also the fundamental difficulty of specifying how the trade offs between health, consumption and other social arguments, as well as the valuation of market and non market activities, ought to be done. This is particularly acute when there is no obvious consensus on how to prescribe social choice, each alternate view generating potential conflicts with other agreed social objectives.

Aims and objectives

The overall aim of the project is to develop a conceptual framework to assess the implications of alternative perspectives, and to undertake a series of case studies to inform the decisions about the appropriate perspective for NICE Technology Appraisal. The project has the following objectives:

(i) To undertake a review of UK policy and of policies adopted elsewhere and to summarise key literature relating to the choice of perspective.
(ii) To develop a formal conceptual framework to distinguish questions of value and fact and assess the performance and likely implications of alternative policies.
(iii) To undertake a series of selected case studies to quantify important non-NHS costs and to illuminate different ways of incorporating these into economic analysis to inform NICE decisions.
(iv) To identify the key issues to be borne in mind when considering the possible policy responses to the problem of appropriate perspective

Structure of the report

The remainder of section 1 provides a review of current UK policy and of policies adopted elsewhere, followed by a focussed review of the key literature relating to the choice of perspective. A conceptual framework is developed in section 2, which allows formal characterisation of three alternative partial policy responses to the problem of perspective. This formulation of the policy problem in section 2.1 allows a more general approach to be developed which can take account of effects external to the health care system while acknowledging fixed budget constraints. The performance of each of these policies are evaluated in Section 2 when changes are marginal, by considering the potential bias they impose compared to the more general case. How the potential for bias changes when the impact on the health care budget is non marginal is explored in Section 2.3. This conceptual framework is also used to explore when transfers between sectors would be useful in Section 2.4, including the implications of non marginal changes and transfers between other budget constrained sectors. The implications of the analysis developed in Section 2 for policy considerations are outlined in section 3. The questions of social value and the choice between a formalised or more deliberative approach are discussed in Section 3.1. These are clearly distinguished from the questions of fact that need to be addressed that are outlined in 3.2. The other critical considerations are explored in Section 3.3. They include consideration of external consumption benefits which may be displaced, the likely dynamic effects on pricing and incentives of research and development, and consideration of effects on other social objectives. Four case studies are presented in Section 4 to illustrate how costs and benefits external to the health care system could be measured and valued and how they might be incorporated into the type of appraisal decisions made by NICE. Each is based on a reanalysis of previous cost-effectiveness evaluations original conducted for the NICE appraisal process. Section 5 provides a summary of potential policy options and the key issues which need to be borne in mind when considering the possible policy responses to the problem of perspective.

1.1. Cost perspective in policy

A review of current UK policy and of policies adopted elsewhere may be instructive. It is also important to ask whether these policies can claim theoretical support in the academic and methodological literature. The purpose of the review of policy and academic literature is to ask whether there is sufficient guidance for policy makers once the reality of fixed budget constraints and the fundamental difficulty of prescribing social choice across all sectors is acknowledged.

Policy in the UK

As economic evaluation methods have become more routinely used to support policy decisions in the UK, documents guiding methodology in this area have become more widespread. However, a clear distinction is evidenced between the methods advocated to inform policy in general, across sectors, and those which have developed in the area of health. HM Treasury's 'Green Book', most recently published in 2003, aimed to 'promote efficient policy development and resource allocation across government' by defining for economic appraisal a 'best practice guide for all central departments and executive agencies'.[3] The emphasis of the report is on the measurement and valuation of all resource

and non-resource consequences no matter where they fall. This societal perspective is consistent with the recommendation of the general methods of cost-benefit analysis as the framework for appraisal – that is, the use of market prices to value the consequences of alternative policy options and, where no competitive market exists, the use of adjusted 'shadow' prices or various forms of willingness to pay methods.

The Green Book has little to say about whether the existence of budget constraints in the public sector has any implications for appraisal methods in general or the choice of perspective in particular. There is an acceptance that budget constraints may exist:

> *'If there is a budget ceiling, then the combination of proposals should be chosen that maximises the value of benefits. The ratio of the net present value to the expenditure falling within the constraint can be a useful guide to developing the best combination of proposals.'*[3] *(p. 37)*

There is not, however, any detailed consideration of what signals budget constraints might represent for policy makers or how projects with resource consequences spilling across budget-constrained public sectors should be analysed and interpreted. Although this is the latest of several similar guidance documents to guide economic appraisal in government and public agencies, there seems to have been no major change in position regarding cost perspective and response to budget constraints from earlier documents.[4]

To some extent, methods guidance to inform economic appraisal in health has taken a consistent line with that in the *Green Book*. The document *Policy Appraisal and Health* was first published in 1995[5] and updated in 2004.[6] It saw itself as providing more specific guidance to the field of health than the *Green Book* but continued to recommend a broad perspective on costs:

> *Economic appraisal aims to identify the best use for society's resources. Consequently it should take account of all the resource costs and savings due to implementation of a policy. In the case of health, this would include resource costs incurred by other support services (including voluntary services), by patients, by their relatives and friends, as well as the costs borne by the NHS. It is often helpful to identify the costs borne by each group separately as well as quantifying the overall resource costs.*[6] *(p. 32).*

Policy Appraisal and Health devoted considerable attention to the quantification of health effects using methods such as QALYs. Again consistent with the *Green Book*, however, the Department of Health focused on the use of willingness to pay methods of various types as a means of valuing QALYs in terms of consumption. Furthermore, they did this without any consideration of the implications for its selected methods on the budget constraints operating in the NHS or other public sectors.

NICE's methods guidance provides a yet more specific set of recommendations about economic appraisal, with a focus on informing its Technology Appraisal Committees' decisions regarding whether to support the use of particular (mainly new) medical technologies in the NHS. Although presumably covered by the guidance in the *Green Book* and *Policy Appraisal and Health*, NICE has advocated rather a different approach to economic evaluation than have those documents. In general, throughout the three sets of methods guidance documents in 2001[7], 2004[8] and 2008,[9] NICE has supported the use of cost-effectiveness analysis, with health expressed in terms of QALYs without valuation of these outcomes in terms of consumption based on external estimates of willingness to pay.

With respect to cost perspective, these documents have consistently indicated that it required resource costs falling on the NHS budget to be the focus of economic evaluations undertaken to support its decisions. Between the 2004 and 2008 documents, however, the position on which costs to consider altered in a subtle but important way. The 2004 document developed the concept of the Reference Case – the combination of preferred methods which should be presented to the Appraisal Committee in at least one part of any submission together with variants of those methods if appropriate. However, the 2004 guidance permitted those submitting evidence to present a wider array of costs if these differed between the options under evaluation, on the basis that they could be 'taken into account' by the Appraisal Committee (although it was indicated that these costs would not normally include productivity costs). In contrast, NICE's 2008 methods guidance document effectively downgraded the role of costs falling outside the NHS budget by supporting their inclusion in economic

evaluations submitted to the Institute only 'in exceptional circumstances' and 'if this has been specifically agreed with the Department of Health, usually before referral of the topic'.

In justifying its preferred cost perspective, NICE has consistently made reference the importance of the NHS budget constraint to its decisions: 'the appropriate objective of the Institute's technology appraisal programme is to offer guidance that represents an efficient use of available NHS and PSS resources' (p. 32)[9] The budget constraint is also central to how NICE conceptualises the range of cost-effectiveness thresholds it uses to make decisions. Here lies the major difference between NICE's recommended cost perspective and those advocated by the Treasury in the *Green Book* and the Department of Health in *Policy Appraisal and Health*: given its defined responsibilities, NICE views the NHS budget as a constraint which needs to be respected in its decisions; whereas the other documents see budgets as largely incidental to establishing efficiency from a broader social perspective.

It should be noted that none of the methods documents reviewed above seeks to justify its position on cost perspective with reference to any underlying principles of how social decisions ought to be made. The *Green Book* (and the *Policy Appraisal and Health* documents which it influences) take it as axiomatic that resource allocation decisions should look at the broad array of social costs, that these should be valued using market prices where possible and shadow prices where they are not. Sector-specific budgets are essentially regarded as an administrative nuisance rather than signalling anything important about social choice. In contrast, NICE is able to justify its narrow views of relevant costs on the basis of its NHS responsibilities.

Policy outside the UK

A large number of jurisdictions have now published guidelines for the use of economic evaluation to support decision making regarding new technologies, mainly pharmaceuticals. Table I summarises what these guidelines require regarding perspective. Of the 26 sets of guidelines reviewed, half require a health system perspective, six require a broader societal perspective, six recommend both a health and societal perspectives as separate analyses, and one indicates no preference. The table also summarises how each guideline seeks to justify its choice of perspective. Where any justification is offered, those adopting a health system perspective typically make reference to the responsibilities of the decision making organisation, and none refers explicitly to a general normative theory. Several of those recommending a societal perspective reference text books and refer to a perceived methodological superiority for that choice.

The table shows that a number of organisations wish to see information on all costs, although their decisions are mainly driven by health system costs. This was NICE's position prior to 2008 and implies that non-health sector costs may be 'taken into account' in some way in decision making. Few of the guidelines explicitly discuss budget constraints in their systems and how they impact on the methods recommended including cost perspective. Where budget constraints are mentioned, only quite general comment are offered. However, a large proportion of organisations require budget impact analyses to support their decision making suggesting that, although there may not be hard constraints, issues of opportunity cost are influencing their choice of preferred methods.

Table I. Recommended perspective in methods guidelines for economic evaluation to support decision making internationally

Jurisdiction/guideline	Perspective recommended	Reasons for perspective chosen	Other details on perspective	Acknowledgment of budget constraint	Budget impact and decision making
Australia	Both a societal perspective and the perspective of the payer are recommended.	Not stated	Not stated	Not stated	Budget impact analyses (BIAs) are relevant to both PBAC and the Australian Government. In the event of a positive recommendation by PBAC, the Australian Government needs utilisation and financial estimates to help provide the necessary funds.
Austria	Apart from the societal perspective, which represents the most comprehensive approach, other perspectives are possible (e.g. the health system, social insurance, hospitals etc).	Not stated	The choice of perspective must be derived logically from the research question.	Not stated	Not stated
Baltic (Latvia, Lithuania, Estonia)	Health care perspective. Societal perspective may be presented only in addition if considered relevant by the applicant.	Not stated	Not stated	Not stated	Not stated
Belgium (KCE)	In the reference case, the perspective of the health care payer (government plus patients) should be used.	Although it is acknowledged that the societal perspective is methodologically more appropriate, the perspective of the health care payer is recommended given the target audience of the guideline, namely, the decision maker.	Broader consequences of a treatment can be taken into account in resource allocation decisions. Other considerations, such as reduction in absence from work, may be important factors in determining the value of a therapy, but this should not be included in the reference case.	It is stated that the cost-effectiveness threshold is very context dependent. It depends, for instance, on the available health care budget and the interventions already financed in a country.	Budget impact of a treatment can be considered by the decision maker, but no specific budget impact analysis is required.
Brazil	The preferred perspective is that of the National Health service, but also the societal perspective is possible.	Not stated	Details on the category of costs that should be included for each perspective are given.	It is stated that any budget constraint associated with the introduction of a technology should be identified and details given.	A BIA should be taken and help making decision on a technology.

Canada (CADTH)	The perspective adopted in the Reference Case should be that of the publicly funded health care system. In some jurisdictions, this perspective may include costs that are incurred by long-term care, social services, or community-based services.	The perspective chosen should fit the needs of the target audience.	The costs associated with adopting a wider perspective should be reported separately where it is likely that they have an impact on the results of the analysis. A very detailed list of category of costs associated with each perspective is provided.	Not stated	A clear distinction between information provided by a BIA and a cost-effectiveness analysis to decision-makers is given.
Cuba	Societal perspective is recommended. Other perspective can be included, but that of the society is mandatory.	The societal perspective is recommended since the decision maker needs to take decisions based on the interest of the whole society.	No other details provided.	In the study discussion, the feasibility of the introduction of a new technology should be stated according to budget constraints.	Study conclusions should take account of the budget impact of a technology.
England & Wales (NICE)	The perspective on outcomes should be all direct health effects, whether for patients or, when relevant, other people (principally carers). The perspective adopted on costs should be that of the NHS and PSS.	The reference-case perspective on outcomes is consistent with an objective of maximising health gain from available healthcare resources. The objective of the NICE's technology appraisal programme is to offer guidance that represents an efficient use of available NHS and PSS resources. For these reasons, the reference-case perspective on costs is that of the NHS and PSS.	Technologies for which a substantial proportion of the costs (or cost savings) are expected to be incurred outside of the NHS and PSS, or which are associated with significant non-resource effects other than health, should be identified and their inclusion approved by the Department of Health during the scoping stage of an appraisal, and these data can be reported separately from the reference case.	Cost perspective justified in terms of the NHS budget constraint.	The potential budget impact of the adoption of a new technology does not determine the Appraisal Committee's decision. However it is important that costs are disaggregated by appropriate generic organization (NHS, PSS, hospital, primary care) and budgetary categories (drugs, staffing, consumables, capital).
Finland	Societal perspective recommended.	Not stated	Not stated	Not stated	Not stated
France	The widest possible perspective is recommended in order to include all relevant outcomes of each programme studied. Thus, the societal perspective is preferred, although other narrower perspective can also be considered.	Since the overall aim of economic evaluation studies is to provide decision aids in the field of public health policy, it would be preferable if a "societal" perspective was adopted in any event. (Ref: Drummond MF., O'Brien	The concept of "societal" perspective as yet has no precise definition in France. Depending on circumstances, it may relate to a concept of collective interest arising out of the economic theory	Not stated	Estimating the short and medium term (2 to 3 years) budgetary consequences for the different agents in the health care system of the implementation of a new treatment is an important secondary objective of economic evaluations.

		B, Stoddart GL et al. Methods for the Economic evaluation of Health care Programmes. 2nd ed. Oxford : Oxford University Press, 1997, p. 17-25)	of well-being, to a general perspective of public health or to the inclusion of concepts of equity between groups and between generations.		
Germany	The perspective of the Statutory Health Insurance (SHI) is recommended. If there are substantial costs borne privately by insured citizens and their families, these should also be included. Any departure from these perspectives should be justified.	Refers to the target audience of the guideline.	Details on costs categories for the SHI are given.	Any technology to receive a positive evaluation must be affordable to the German payers.	Budget impact is fundamental in decision-making. There may be circumstances where a technology is efficient but a BIA suggest that affordability can be a problem.
Hungary	If the objective of the study is to influence public financing of healthcare interventions, the study perspective should be that of the financer or purchaser organisation. However, it is also desirable to provide results from a broader societal perspective.	The choice of healthcare perspective is related to the target audience. However, optimal resource allocation at the societal level is a desired objective and the additional analysis from societal perspective minimises the risk of excluding aspects that may be of significance to decision makers.	Details on cost categories for each chosen perspective are given.	Rationing is necessary to avoid a rapid increase in healthcare expenditure.	Details should be provided on the impact of the intervention on the different healthcare budgets. This allows decision makers to make better informed decisions and to plan healthcare budgets taking into consideration the full consequences of including new cost-effective treatments. The budget impact analysis should cover 3 to 5 years.
Ireland	No specific perspective recommended. It is only recommended that “The perspective adopted for the analysis (health care system, society) should be clearly stated and explained”.	Not stated	Not stated	Not stated	Not stated
Israel	The perspective of the Sick Funds of the National Health Insurance is recommended.	Not stated	Not stated	Not stated	The budget impact of a new treatment (over three years) for the Sick Funds of the National Health Insurance should be determined and can help taking decisions.
Italy	Societal and NHS perspectives are recommended. Other perspectives could be useful as sub-analysis.	Not stated	Not stated	Not stated	A budget impact analysis for the first two years after the introduction of a technology is recommended but no details are given on the impact of this analysis of decision making.

Mexico	Mexican health system. If relevant, the analysis can include results from some perspective in particular (one particular institution or the social perspective), in addition of the public health perspective.	If the study's objective is to have an influence in obtaining public financing for health interventions the study's perspective should be that of the public health sector.	Not stated	Not stated	Not stated
The Netherlands	The evaluation should be performed and reported from a societal perspective.	There is broad consensus nationally and internationally that the societal perspective is the most appropriate choice (ref. Gold MR, Siegel JE, Russell LB et al. Cost-effectiveness in health and medicine. Oxford University Press, 1996). In addition, the reimbursement question involves the allocation of financial means and consequences for public health.	Not stated	Not stated	Not stated
New Zealand	The perspective of the payer is recommended (with respect to PHARMAC decisions).	PHARMAC's objective is to maximise health gains from health sector funds. If societal costs were included in analyses, this could result in PHARMAC considering issues it has no control over.	PHARMAC has a separate budget from other government sectors; hence any patient benefits and/or costs that accrue beyond individual health outcomes are outside the scope of PHARMAC's control.	Not stated	A budget impact analysis over 5 years is recommended, but no details on its impact on decision-making are given.
Norway	Both the perspective of the society and that of the payer (National Insurance Administration) are accepted.	Not stated	Not stated	Not stated	Not stated
Poland	It is recommended to use the perspective of the financing health care service (public payer, patients, other payers). In addition, a separate analysis using the societal perspective is suggested.	The societal perspective has the advantage to minimise the risk of failing to include aspects that might have an impact on decision making.	Not stated	Not stated	A very detailed description of the budget impact analysis is given that it is mandatory (at least 2 years time horizon). The BIA provides information on the possible impact of adopting a decision of reimbursing a new technology.
Portugal	The perspective of the societal is recommended.	All the relevant costs and consequences should be analysed before listing alternatives in order of	Society's perspective should be broken down into other relevant points of view, with special attention	Not stated	Since almost all studies are conducted to help public financers reach their decisions, it is recommended that, if appropriate,

		importance, regardless of who ordered the study.	to the third payers if they are the users of the study.		an estimate should be made on the effects on their budgets.
Russian Federation	Several perspectives are allowed including societal, federal health care system, institutional, private practice, patients and family, medical insurers.	The perspective should be in line with the objective of the analysis.	Not stated	Not stated	Not stated
Scotland	It is recommended to use the perspective of the Scottish health care system, patients and their families.	Not stated	An indication of the nature and likely magnitude of any excluded benefits and costs that would arise from adopting a wider societal perspective and the effect of including these in the cost-effectiveness analysis should also be provided.	Not stated	Not stated
Spain	It is recommended to adopt both a societal perspective and the perspective of the third party payer (healthcare system).	The societal perspective includes all costs and benefits to the whole society, thus it minimises the risk of excluding relevant factors. The perspective of the healthcare system is necessary since it is the payer of health services in Spain.	If only the third-party payer perspective is adopted, this should be justified by the authors (e.g. societal costs are irrelevant).	Not stated	BIAs (recommended over 3 or 5 years) can help taking decisions on the suitability of a new technology in addition to its cost-effectiveness.
Sweden	The societal perspective is recommended.	Not stated	Not stated	Not stated	Not stated
US (AMCP)	The payer perspective is recommended for the primary analysis. A societal perspective analysis as a secondary evaluation is also suggested.	Not stated	Not stated	The goal of the formulary review process is to provide a quality pharmaceutical benefit, determined through an evidence-based decision-making process, taking into account the reality of constrained health care budgets.	It is fundamental to distinguish between cost-effectiveness models and BI models which provide different information to the decision-maker. In practice the selection of the most efficient mix of programmes, given a budget constraint depends on whether alternative programmes are mutually exclusive and whether the scale of programmes can be changed without changing their incremental cost-effectiveness ratios.

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Brazil: de Miello Vianna CM, Caetano R. Diretrizes Metodológicas para Estudos de Avaliação Econômica de Tecnologias para o Ministério da Saúde. 2007

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Germany. *IQWiG - Institute for Quality and Efficiency in Health Care. *Methods for Assessment of the Relation of Benefits to Costs in the German Statutory Health Care System*. 2008

Hungary: Szende A, Mogyorosy Z, Muszbek M et al. Methodological guidelines for conducting economic valuation of healthcare interventions in Hungary: a Hungarian proposal for methodology standards. Eur J Health Econom 2002; 3: 196-206

Ireland: National Centre for Pharmacoeconomics - *Irish Healthcare Technology Assessment Guidelines* 1999

Israel:Pharmacoepidemiology and Pharmacoeconomics Department (Ministry of Health) - *Guidelines for the submission of a request to include a pharmaceutical product in the national list of health services.* 2002

Italy: Capri S, Ceci A, Terranova L et al. *Guidelines for economic evaluations in Italy: recommendations from the Italian group of pharmacoeconomic studies.* Drug Information Journal 2001; 35: 189-201

Mexico: National Institute of Public Health Center for Health Systems Research Health Economics and Evaluation Division. *Development of guidelines for conducting economic evaluations of health interventions in Mexico*

The Netherlands: CVZ- The Health Care Insurance Board. *Guidelines for Pharmacoeconomic Research in the Netherlands*. *Updated Version*. 2006

New Zealand: PHARMAC — Pharmaceutical Management Agency. *A prescription for pharmacoeconomic analysis.* Version 2, 2006

Norway: The Norwegian Medicines Agency: *Norwegian guidelines for pharmacoeconomic analysis in connection with applications for reimbursement.* 2004

Poland: Agency for Health Technology Assessment in Poland. *Guidelines for Conducting Health Technology Assessment*. *Version March 27*

Portugal: INFARMED — Instituto Nacional da Farmácia e do Medicamento. *Guidelines for economic drug evaluation studies*. 1998

Russian Federation: Branch Standard. The standardization system in the Russian federation health care system. Clinico-economic studies. Prepared for the Ministry of Health 2002.

Scotland: SMC – Scottish Medicines Consortium - *Scottish Medicines Consortium Economic Guidance*. 2002

Spain: López Bastida J, Oliva J, Antoñanzas F et al. P*ropuesta de guía para la evaluación económica aplicada a las tecnologías sanitarias*. Madrid: Plan Nacional para el SNS del MSC. Servicio de Evaluación del Servicio Canario de la Salud; 2008

Sweden: The Pharmaceutical Benefits Board - General guidelines for economic evaluations from the Pharmaceutical Benefits Board. 2003. (Now renamed the Dental and Pharmaceutical Benefits Authority (TLV)

United States

*AMCP - The Academy of Managed Care Pharmacy. *The AMCP Format for Formulary Submissions.* Vesion 2.1., 2005

1.2. Economic evaluation methods literature

The methods guidelines of most of those organizations making decisions about health care resource use reviewed in the previous section indicate a preference for cost-effectiveness methods.[10] For example, those organizations which have required formal economic evaluation for the longest include the provinces of Canada, the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia and NICE in the UK. Each of these organisations either formally requires (NICE) or prefers (PBAC and Canada) cost-effectiveness analysis with QALYs as the measure of health effect.[9,11,12] This contrasts with the methods of economic evaluation used to inform resource allocation in other public sectors in the UK. In the UK, the Department of Transport, for example, generally applies cost-benefit analysis (CBA) to guide decision making, as described and advocated in the *Green Book.*

It has been argued that an advantage of CBA is that it is more consistent with the normative principles of welfare economics.[13] It would be more accurate to say that CBA is an 'applied arm' of neo-classical welfare economics which is founded on four key tenets:[14] that individuals maximize utility rationally on the basis of their preferences; that individuals are the best judge of their utility; that utility is derived only from outcomes rather than processes; and that the social desirability of alternative 'states of the world' should be founded only on their impact on the utility (welfare) of individuals as revealed by their preferences. Importantly, these principles mean that individual preference alone reveals social welfare. Since it is impossible to directly compare individual utility without violating key tenants above, the guidance offered to social choice is limited to situations in which one or more individuals regard themselves as better off but none regards himself/herself as worse off. For applied policy guidance, a compensation principle is adopted where a state is more desirable (social welfare improves) if those that gain could in principle compensate those that lose. If markets are complete, competitive and undistorted then market prices reveal preference and social value. They represent the compensation individuals require so a simple comparison of the benefits and costs valued at markets prices is all that is required, i.e. market prices reveal individual preferences and therefore social value. If markets are distorted, shadow prices which adjust for distortions can be derived. Where a market does not exist (e.g. for health) shadow prices can be derived from preferences revealed in other markets and activities or expressed directly in hypothetical situations. The main tenets and their variants have been referred to as 'Welfarist'.[14,15]

Given the widespread use of CEA in economic evaluation in health, there have been a number of papers which have sought to locate these methods in neo-classical welfare economics and to establish the conditions under which CBA and CEA would generate the same conclusions.[2,16-19] In general terms this has required some strong assumptions, perhaps most notably that the QALY can be formally considered a utility which implies that individuals are risk neutral with respect to life-years for all health states and that additive utility independence applies with respect to time periods.[20]

Some of these papers have explicitly considered the appropriate cost perspective for cost-effectiveness analysis within this Welfarist paradigm. Garber and Phelps concluded that the inclusion of the full social cost of extending life (in terms of health care and productivity costs) would make no difference to the relative ranking of health care interventions under appraisal.[18] Using a similar framework but relaxing some key assumptions, Meltzer reached the opposite conclusion: that cost-effectiveness analysis will only reach conclusions consistent with the tenets of Welfarism if all costs are considered, including the effects on all future (related and unrelated) medical expenditures, consumption and productivity.[2]

From the same general normative viewpoint, Johannesson and O'Conor[19] considered the arguments for a societal perspective when decisions are based on comparing the incremental cost per QALY gained of an intervention with a fixed cost-effectiveness threshold determined on the basis of societal willingness to pay. The authors argued that, for this approach to CEA to be consistent with the maximization of societal welfare, all costs need to be factored into the analysis, no matter where they fall. Again, a number of strong assumptions were required in order for this approach to CEA to be consistent with societal welfare maximization including the need for the marginal utility of income relating to the costs of funding health care to be the same for all health care financing programmes. Johannesson and O'Conor also present some more general arguments against a cost perspective of a specific health care budget. These include the fact that few health care systems are financed from a single budget (e.g. the plurality of funding arrangements in the US) and that budgets are typically annual which requires a highly truncated time horizon for economic evaluation.

A common feature of those studies assessing whether decisions based on CEA with QALYs can be consistent with a Welfarist normative framework is that they offer no consideration of the role for health sector budgets. In effect, budget constraints are viewed as an administrative nuisance rather than expressing an indication of social value. Critically, there is little acknowledgment of the importance of the opportunity costs that they induce. Jonsson offers ten reasons why a societal cost perspective should be adopted for economic evaluation. Many of these relate to the importance of *decision making* from a societal perspective – that public systems should consider all costs and effects.[13]

The key tenets of neo-classical welfare economics as a basis for social choice have been questioned and a range of alternative normative principles suggested. This alternative framework has been termed 'Extra-Welfarism'.[14,21] Although a number of variants can be identified, the general features of this framework are that a number of measures of 'wellbeing' and 'outcome' can guide social choice as well as (or instead of) individual preference, that various constituencies might be used to value these measures rather than just the affected individuals and that interpersonal comparison is explicitly permitted.[14] In the field of health, this is consistent with the use of health gain as an important outcome in applied economic evaluation. One of the strands of Extra Welfarism is the 'decision making' approach described by Sugden and Williams.[22] This identified a legitimate role for economic analysis to explicitly consider the objectives and constraints of the decision maker in guiding the choice between policy options. To some extent, this view of economic appraisal is consistent with the practice of much cost-effectiveness analysis in health: although the valuation of health outcomes is typically based on the preferences of a sample of patients or the public, distributional issues and broader equity arguments invariably remain in the domain of the decision maker within some form of deliberative process.[23]

One important constraint facing many decision making bodies relates to the budget for which they are directly or indirectly responsible. Hence a budget-specific focus in a piece of economic analysis would be entirely consistent with Sugden and Williams decision making approach. However, some have advocated a broad societal cost perspective despite eschewing some Welfarist prescriptions. The US Panel on Cost-Effectiveness in Health and Medicine, for example, defined a Reference Case in which QALYs took the role of the main outcome and willingness to pay methods were explicitly rejected because of their distributional implications.[24] The US Panel does, however, strongly advocate a societal perspective on costs, although this is not justified with reference to the tenets of neo-classical welfare economics. Rather, they justify this recommendation in terms of the Rawlsian veil of ignorance: uncertainty about which individual in a society one will be, provides a moral case for considering all costs, no matter on whom they fall. The decision making approach appears to have played little role in supporting the US Panel's deliberations, perhaps because of a wish to abstract itself from the complexity of multiple health care systems in the US and to develop a set of general principles.

The decision making approach as a justification for a budget-specific cost perspective is further developed by Claxton *et al.*[25] They argue that budgets can be seen as more than administrative mechanisms. At least within liberal democracies with universal health care systems such as the UK NHS, the setting of the health care budget can be seen as a legitimate expression of social values albeit a complex and imperfect one. The use of cost-effectiveness analysis to support decision makers' attempts to maximize health subject to this budget constraint is seen, therefore, as entirely appropriate. This explicitly uses the shadow price of the budget constraint, in the form of a cost-effectiveness threshold, to permit a comparison of health gain from new interventions and programmes with the health decrements associated with any displaced activity in the system which is necessary to fund it. The authors do consider, however, how 'spillovers' in the costs and consequences of health system interventions to other sectors (public and private) may be handled within the decision making approach. Rather than ignoring the budget constraints set for health and other sectors, a compensation test is suggested. For example, if a health care intervention generates a net health decrement because of the opportunity costs it imposes on the health care budget but produces resource savings to the education sector, could the latter compensate health to provide the intervention such that both sectors experience no decrement in their respective objective function? The implementation of an approach would, of course, require periodic transfers between public sectors and indeed between public sectors and the private sector.

1.3. Summary

The review of current UK policy and of policies adopted elsewhere reveals considerable variation in the type of perspective claimed, a lack of clarity on what constitutes a broad societal perspective and little or no consideration of the impact of fixed budgets. The justification for type of policies adopted is also somewhat limited, commonly resting on literature which ignores the implications of fixed budget constraints. This lack of clarity and ambiguous terminology is also reflected in the results of a recent extensive review of the cost perspective adopted in published cost-effectiveness literature, with many studies claiming to take a societal perspective when in fact their analysis is restricted to the health care system.[26]

There has been a long tradition of neo-classical welfare ('Welfarist') economics guiding social choice. In terms of applied economic appraisal, there have been many movements away from its main tenets. In UK guidelines, this tradition was reflected in the recommendations of the *Green Book* and, in turn, in the Department of Health's *Policy Appraisal in Health*. However, the *practice* of economic evaluation in health has generally taken a markedly different approach, and there has been a corresponding development in normative *principles* to accompany this. Although it has many variants, this Extra Welfarist normative framework can be used to justify an approach to economic appraisal which focuses on the needs to decision making and, in particular, a budget-specific cost perspective. It would be wrong, therefore, to conclude that the use of cost-effectiveness analysis with a narrow cost perspective is bereft of any grounding in normative theory. However, for decision making by pubic agencies where interventions and programmes have multiple consequences, some of which fall outside the budget of interest, there remains a need to consider how best to reflect these external effects whist still respecting sector-specific budgets.

2. A conceptual framework

Decisions based on cost-effectiveness analysis are most commonly characterised as comparing the benefits expected to be gained in the health sector, often measured using QALYs, to the health that is likely to be forgone due to additional cost falling on the health care budget. This type of decision rule is reasonable and complete if: i) the social objective is to improve health; ii) the measure of health gained and forgone captures 'enough' aspects of social value; iii) the budget for health care is fixed or at least it is not within the remit of the decision making body to increase or reduce overall expenditure on health care. However, it also relies on two more assumptions which are unlikely to hold: i) that all the additional costs of using the technology fall on the budget constraint so that all costs are actually health forgone; and ii) all the benefits are in the form of health and there are no external effects on other sectors including productivity and consumption in the private sector. For ease of terminology we refer to all external effects falling on the wider economy as (net) consumption costs which will be made up of costs imposed on the private sector (valued in terms of consumption forgone) and benefits accruing to the private sector (valued in terms of consumption gained).

However, in the face of budgets set by a socially legitimate higher authority it is not clear how or whether a broader social perspective which would include all effects on all sectors should be implemented – particularly if transfers between sectors are not possible. The review of current polices (in the UK and elsewhere) shows that there is limited theoretical support for the type of approaches adopted in the academic and methodological literature. Indeed, the review of this literature shows that there is limited guidance for policy makers once the reality of fixed budget constraints and the fundamental difficulty of specifying an explicit social welfare function to describe social choice across all sectors are acknowledged.

In the face of these difficulties current policies can be regarded as lying on a spectrum ranging from ignoring the fact of fixed constraints to acknowledging the constraints but ignoring the effects external to the health care system. There are three alternative partial responses to this difficult allocation problem that can be usefully characterised and which are examined and evaluated in more detail below:

A *Ignore the wider costs outside the health sector*
In essence this is the NICE approach after the revision of its methods guide in 2008. Prior to 2008 the methods guide was more permissive. Although wider costs were not part of the reference case in the 2004 guidance, it was suggested that a non reference case analysis which included them would be taken into account in the deliberative process.

B Treat any wider costs as if they fall on the budget constraint
This represents a rather naive view that all costs should be included but decisions should still be based on comparing the resulting incremental cost-effectiveness ratio (ICER) with the current threshold, where the threshold represents what health is likely to be forgone (the reciprocal of the shadow price of the constraint). This is a characterisation of the position of some consultees and appellants during a number of NICE Technology Appraisals including the applicants during Judicial review in 2007.

C *Ignore the budget constraint*
This represents the greater part of literature on evaluation outside health (cost-benefit analysis), where the fact of exogenous budget constraints and the implication for opportunity costs are rarely acknowledged and even less commonly dealt with analytically. It also represents the implicit view of those who argue that the cost-effectiveness threshold should reflect some social consumption value of health rather than what is forgone in a budget constrained system.

To examine the different approaches in more detail and to evaluate them by establishing the conditions under which each my lead to 'poor' decisions by NICE, we develop a simple but formal conceptual framework. In doing so, we make a number of simplifications to improve intuition and clarity without loss of generality.

i) Initially we consider only two sectors: health care and the wider economy; where all external effects use the common numeraire of consumption. Later in Section 2.4 this is relaxed to

consider two budget constrained public sectors (health and education), and to explore the impact of transfers within the public sectors and between the public and private sectors.

ii) Throughout we consider costs and health benefits falling in a single period. The generalisation to multiple periods and accounting for rates of time preference, growth in consumption value of health and growth in the threshold is has been dealt with elsewhere.[27]

iii) It becomes apparent in Section 2.1 that when there are external effects, some notion of a 'consumption value of health' is required. Although we do not formally specify a welfare function, it is at least initially assumed to be separable in health and consumption, primarily to simplify the notation and ease exposition. This could be interpreted as welfarist or extra welfarist depending on how v is derived and some simplifying assumption about how health and consumption enter individuals utility functions. Other specific and more complex welfare functions could be substituted but they would not change the fundamental insights or considerations. We discuss the difficulty of a more complex and latent welfare function later in this chapter and in the next.

iv) Throughout subsequent sections we assume that the cost-effectiveness threshold (k) will be less than some social consumption value of health (v). This reflects the current debate, including current estimates of the threshold[28] and the type of values and estimates proposed for v.[29] Aside from empirical observations there are good reasons why the threshold, which could be taken to represent how much society wishes to pay for improvements in health delivered by collectively funded health care, might differ from how much of their own consumption individuals are willing to give up to improve their own health. There are also a number of reasons why a social democratic process may not be expected to deliver budget allocations which precisely match individual preferences (see Section 3.1 for a more detailed discussion).

v) To simplify the notion and exposition in Section 2 we focus on the net consumption costs or benefits offered by a new technology and initially assume that the health care activities which are displaced will have no net consumption costs or benefits associated with them, i.e., it is assumed $\Delta c_c = 0$ for displaced health care. The fact that the costs of a new technology will displace other health care activities which may be associated with net consumption benefits or costs as well as health gains is a critical consideration which is discussed in Section 3.3.

Initially, in Section 2.1, the allocation problem is formulated within the health sector using three equivalent decision rules for cost-effectiveness. These decision rules are generalised to two sectors and we demonstrate the circumstances under which current NICE policy would be correct. In doing so, we outline two very different approaches to economic evaluation which turn on normative questions of social value. In Section 2.2 the three possible approaches to multi-sector effects are then evaluated when the project being considered can be regarded as a marginal change: that is, when the health care or consumption costs are so small relative to the budget or the wider economy, respectively, that acceptance would not change the cost-effectiveness threshold or the consumption value of health. However, repeatedly making decisions, each of which might be regarded as marginal, will lead to non marginal changes, i.e., all repeated changes in a similar direction will be non marginal in the long run. Therefore, Section 2.3 re-evaluates each approach when changes are non marginal. Section 2.4 examines the possibilities of making transfers, in the two sector and multi sector case, between budget constrained public sectors and between the public and private sector. In each case we identify the additional value of transfers and how to identify the value of the transfers that would be needed. The conceptual framework and basic analytics of this chapter provide the basis of the discussion of policy implications in Chapter 3 where the critical assumption of being able to specify an explicit social welfare function to describe social choice across sectors as well as assessment of displaced consumption and dynamic effects are examined.

The notation used is defined in the text as it appears. However, all the notation used in this chapter is also summarised in Table II for quick reference.

Table II Notation used throughout

Symbol	Definition
k	Cost-effectiveness threshold (the additional costs that would displace 1 unit of health elsewhere in the health care system)
v	The consumption value of health (the amount consumption regarded as equivalent to 1 unit of health)
Δh	Incremental health benefits
Δc_h	Incremental costs required to achieve Δh which fall on the budget for health care
Δc_c	The net effects which do not fall on the budget expressed as a net consumption cost to the wider economy
k^*	Cost-effectiveness threshold for a non marginal change

2.1 Formulation of the problem

There are quite profoundly different, but quite reasonably held, views about the role that economic analysis ought to play in social choice,[30,31] particularly in health.[14] These views partly explain the different positions that can be taken and expose the key questions of fact and of social value at the heart of this policy question. Therefore, we draw attention to these at the outset but discuss their implications more fully in Chapter 3.

Cost-effectiveness analysis is commonly seen as a means of maximising an exogenous (explicit and agreed) objective, commonly health itself, subject to an exogenous budget constraint.[24,32] Decisions can be based on either net health or monetary benefit [33,34] or by comparing the ICER to a cost-effectiveness threshold which represents the cost-effectiveness of the health care which will be displaced.[35] Assuming divisibility and constant returns,[36,37] this is equivalent to a mathematical programming approach where the cost-effectiveness threshold is the reciprocal of the shadow price(s) of a single budget constraint [38] or a series of budget constraints over multiple periods.[39]

In these circumstances CEA cannot be used to make claims about social welfare or the optimality or otherwise of the budget for health care. Its role is more modest, claiming to inform social decisions in health rather than prescribing social choice. It is this role that CEA has tended to play in policy. Furthermore, it fits well with the view[25] that bodies such as NICE in the UK can be appropriately treated as the agent of a socially legitimate higher authority which is unable to express an explicit and coherent social welfare function[a]. In these circumstances agents (such as NICE) can be regarded as delegated authorities but ones that cannot be asked to improve social welfare, since it cannot be specified. Rather, budgets are allocated by the higher authority and are accompanied by a set of explicit and specific objectives (e.g., to improve health in the case of NICE) for the agents to employ. The implications of this process (i.e., the shadow prices of the constraints imposed by the higher authority) are a partial social expression of some unknown underlying latent welfare function.

Current NICE policy

The implications for policy and decision rules can be illustrated using a simple allocation problem where a new technology is compared to a single alternative (e.g., current clinical practice). A social decision maker such as NICE has estimates of both the technology's expected incremental health benefits, Δh, and the incremental costs falling on the health care budget, Δc_h. The social decision maker faces an exogenous budget and has an estimate of the cost-effectiveness threshold, k, reflecting the reciprocal of the shadow price of the budget constraint.[40],[41] Assuming that all costs fall on the budget constraint, the expected health forgone in each period due to the additional costs of adopting the technology is $\frac{\Delta c_h}{k}$. Since all costs fall on the health care sector (no costs fall on private consumption in the wider economy) all costs are health forgone.

[a] Legitimate higher authority can be thought to rest with the process rather than individuals within it. For example, in a social democracy it does not rest with an individual (e.g., a Minister), or particular Departments (e.g., Treasury), or even Government, but with the whole process, including Government, the various processes of parliamentary scrutiny and the wider context of civil society (the judiciary, professional civil service etc).

Allocation decisions made by a body such as NICE can be described as comparing the health expected to be gained and forgone, and accepting those technologies where the former exceeds the latter, i.e., accept the technology if the net health benefit is positive:

$$\Delta h - \frac{\Delta c_h}{k} > 0 \qquad (1)$$

Alternatively and equivalently, these decisions can be expressed as a more familiar comparison of the ICER with the threshold, k. The net health benefits in (1) can be rearranged to provide an ICER which should be less than k if the technology is to be accepted:

$$\frac{\Delta c_h}{\Delta h} < k \qquad (2)$$

Both (1) and (2) are also equivalent to asking whether the monetary value of the health gained (Δh rescaled to money terms using k) exceeds the costs i.e., the threshold is used as an expression of what society wishes to pay for health delivered through collectively funded health care. Now the technology should be accepted if the net monetary benefit is positive:

$$k.\Delta h - \Delta c_h > 0 \qquad (3)$$

These three (equivalent) decision rules are complete and will be appropriate if the social objective is to maximise health, if all costs fall on the health care sector and if all benefits of social value are in the form of health. However, if there are effects (costs and benefits) which fall outside the health sector, e.g., on the wider economy then this characterisation is inadequate and needs to be generalised

The more general case

In most circumstances there are effects outside the health sector. For example, there may be direct costs of care which do not fall on the NHS budget such as the cost of caring for a patient with chronic disease. There are also the external effects on the wider economy which might include the net contribution of returning a patient to activity in the labour market (value of their future productivity net of future consumption). To take these into account formally when making decisions within the health sector some means to value heath gained and forgone within the health sector relative to costs and benefits falling on the wider economy is necessarily required. The rates at which society is willing to trade social arguments including health and consumption is commonly described as a social welfare function.

As described in Section 1.2, economic analysis has traditionally taken a wider view of social objectives than simple sector-specific outcomes.[15,42] Such a role for economic analysis is more ambitious; providing a means of making statements about social welfare but also requiring the specification of an explicit social welfare function which will have more than health as its arguments. This view is well represented in the CEA and CBA literature. The definition of social welfare can be based on individual preferences, expressed or revealed (a 'Welfarist' view) or modified by other social arguments (an 'Extra Welfarist' view). [2,43] Importantly, it prescribes social choice rather than simply informing social decision makers (agents) within the confines of the health care system (or other sectors). Most commonly it has been used while making the (often implicit) assumption that either budgets are necessarily set to be optimal with respect to the presupposed welfare function or are not actually fixed, with the decision making body effectively having a remit to increase or reduce expenditure on health care. It is this view of the role of economic analysis that underpins the reasoning and recommendations in the Treasury Green book and other Department of Health policy documents as discussed in Section 1.2. [3,5,6] It should be noted that the Green book does recommend that the opportunity costs associated with budget constraints should be accounted for but it provides little detailed guidance on how this ought to be done, especially when there are impacts on multiple sectors.

This more traditional approach is less well represented in decisions about health technologies, partly due to the difficulty of identifying any welfare function carrying some broad consensus or social legitimacy, [31,44] particularly when considering decisions with direct health impacts. Nevertheless, health must inevitably be traded-off against other aspects of social value, most notably consumption,

by social decision makers: whether this is done implicitly by a higher authority setting the budget constraints or more explicitly using some specified social welfare function. This trade-off becomes particularly apparent once effects outside the health sector are acknowledged.

The implications for policy and decision rules can be illustrated using the simple allocation problem above, but now accounting for the possibility of costs and benefits outside the health sector expressed as a net consumption cost, Δc_c. Now the allocation decision described in (3) can be generalised to comparing the consumption value of the health expected to be gained to the consumption value of health forgone and other net effects on consumption. The social consumption value of health, v, represents the amount of consumption that is equivalent to 1 unit of health. Within this framework, the technology should be accepted if the net consumption value is positive:

$$v.\left[\Delta h - \frac{\Delta c_h}{k}\right] - \Delta c_c > 0 \qquad (4)$$

The health expected to be gained is valued at v rather than k. But since all costs that fall on the health care budget are also health forgone these must also be valued at v (the first term). Therefore, if there are no external effects ($\Delta c_c = 0$) a decision based on (3) or (4) will be the same irrespective of the value of v. When there are no external effects, maximising health or maximising the consumption value of health leads to the same decision: the value of v and whether or not $v > k$ is irrelevant, what matters for the decision is the value of k (there are, however, some implications for discounting which are discussed elsewhere).[27,45]

When there are external effects ($\Delta c_c \neq 0$) the decision can be described as a comparison of the consumption value of the net health gained in the health sector (the first term) with the net consumption costs falling on the wider economy (the second term). If the former exceeds the latter then the technology should be adopted. This will be complete and appropriate if a number of assumptions hold: i) if transfers between sectors are not possible, then Δc_h must be marginal with respect to the budget, i.e., incurring these additional costs will not change the cost-effectiveness threshold; ii) more credibly, Δc_c must be marginal with respect to total consumption in the wider economy so that incurring Δc_c will not change v; and iii) the value of v must be a complete and socially legitimate value of health. Among other things this last assumption requires that either health and consumption are the only arguments of social value; or that they are separable from all other potential arguments in some more complex and complete welfare function. All of these assumptions will be examined in more detail in subsequent sections.

Consumption is not the only numeraire that can be used. Alternatively and equivalently the allocation decision in (4) can be expressed in terms of health:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} > 0 \qquad (5)$$

Now the decision can be described as a comparison of the net health gained in the health sector (1st term) with the health equivalent of the net consumption costs falling on the wider economy (2nd term). If the former exceed the latter then the technology should be adopted.

This formulation may help to understand NICE policy prior to 2008 and other jurisdictions, where wider costs are 'taken into account' in an implicit deliberative way. For example, if $k = £20,000$ but $v = £60,000$ then costs which fall outside the health sector get one third of the weight $\left(\frac{k}{v}\right)$ of costs that fall directly on the NHS budget. This can be clearly seen when (5) is rearranged to express the decision as a comparison of an ICER, which includes both Δc_h and Δc_c, with the threshold:

$$\frac{\Delta c_h + \frac{k}{v}\Delta c_c}{\Delta h} < k \qquad (6)$$

Therefore, NICE policy prior to the 2008 Methods Guide could be interpreted as an implicit response to these issues, where wider effects where 'taken into account' as an additional consideration, i.e., they where not given the same weight as costs falling on the NHS budget (see discussion of B in section 3.2 below), but neither were they given zero weight and ignored (see discussion of A in section 2.2 below). The approach could be thought of as placing policy between the two extremes of attaching weights of zero or one to Δc_c.

A more deliberative approach to this problem rather than adopting formal and explicit analytical rules might reflect the fact that that the cost impact on the NHS of these considerations will ultimately be non marginal. Although, this will unambiguously reduce the threshold (all other things equal), the magnitude of the reduction will be unknown or at least very uncertain. It might also reflect the fact that there is generally no broad consensus or obvious social legitimacy for any particular welfare function and the consumption value of health derived from it. Finally, even if a consumption value of health was regarded as acceptable, the welfare function it presupposed is unlikely to capture everything of social value. Again this general difficulty is reflected in the way NICE attempts to deal with a range of other social arguments described in its social value judgements document - that is, through deliberation.

The current policy of assigning zero weight to Δc_c, however, appears, at first, to be more difficult to justify since it would only be appropriate if either there were no measureable external effects or if the consumption value of heath was so much greater than the cost-effectiveness threshold that any external effects would carry negligible weight. Nevertheless, the other alternatives which have been proposed to NICE's current (post 2008 position) may not necessarily offer any improvement. Indeed the discussion of implications and considerations in Sections 3 and 5 suggests there may be potential dangers Each of these alternatives are examined when changes are regarded as marginal in the next section, before the effect of non marginal changes is examined in more detail in Section 2.3.

2.2 Marginal changes

In the face of these difficulties current policies can be characterised as three alternative partial responses or decision rules: i) ignore the wider costs outside the health sector; ii) treat any wider costs as if they fall on the budget constraint; and iii) ignore the budget constraint. Each are evaluated in turn, considering the direction and potential size of any bias in terms of net health benefit by comparison with the more general and complete decision rule expressed in (5) above.

Importantly in this section it is assumed that transfers between sectors are not possible but that all changes are marginal. That is, Δc_h must be marginal with respect to the budget, i.e., incurring these additional costs will not change k; and ii), Δc_c must be marginal with respect to total consumption in the wider economy, i.e., incurring Δc_c will not change v. In addition, we assume that $k < v$ to reflect current debate, proposed values and the reasoning outlined in Section 3.3.

For each of the three alternative decision rules their potential bias is illustrated when the technology is expected to offer positive health benefits ($\Delta h > 0$), and when there are either net consumption costs ($\Delta c_c > 0$) or net consumption benefits ($\Delta c_c < 0$) on the wider economy. In each case the additional health care costs may be positive or negative, i.e., when $\Delta c_h < 0$ the technology expected to save NHS resources. The other possibilities when $\Delta h < 0$ are reported in Table III. The implications of taking a wider perspective in these circumstances are briefly discussed. Simple numerical examples are used throughout to illustrate the decision rules and potential bias using common values of $\Delta h = 1$, $k = £20,000$ and $v = £60,000$.

A Ignore effects outside the health sector

In essence this characterises the NICE approach after the revision of its methods guide in 2008. When expressed in net health benefit this decision rule was given in (1) above. The difference between equation (1) and the general and more complete decision rule in (5) is equal to a bias of,

$$\frac{\Delta c_c}{v} \qquad (7)$$

This represents the extent to which cost-effectiveness will be overestimated when using the simple and incomplete decision rule, i.e., when it is positive the bias favours the technology, there is a danger that it will be approved when it should be rejected. When the bias is negative it will disadvantage the technology and there will be a danger of rejection when it should be approved.

Net consumption costs ($\Delta c_c > 0$)

When there are net costs falling on the wider economy ($\Delta c_c > 0$) there is an unambiguously positive bias in favour of the technology. The use of simple decision rule in (1) neglects the positive costs falling on the wider economy and there is a danger that the technology will be approved when it should be rejected. For example, if $\Delta c_h = £10,000$ and $\Delta c_c = £60,000$ then the true net health benefit would be:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£10,000}{£20,000}\right] - \frac{£60,000}{£60,000} = -0.5,$$

and it should be rejected. However, the net health benefit will be overestimated if Δc_c is ignored,

$$\Delta h - \frac{\Delta c_h}{k} = 1 - \frac{£10,000}{£20,000} = 0.5$$

and a technology that should be rejected would be wrongly accepted. Clearly, the size of this bias and the danger of a wrong decision will greater when the consumption costs are larger and when the consumption value of health is lower.

If the technology saves NHS resources ($\Delta c_h < 0$) there remains an unambiguously positive bias in favour of the technology which could lead to a technology being accepted when it should be rejected. For example, if $\Delta c_h = -£10,000$ but $\Delta c_c = £120,000$ then the true net health benefit would be

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{-£10,000}{£20,000}\right] - \frac{£120,000}{£60,000} = -0.5$$

and it should be rejected. The net health benefit would be overestimated using the simple decision rule:

$$\Delta h - \frac{\Delta c_h}{k} = 1 - \frac{-£10,000}{£20,000} = 1.5$$

Using the simple decision rule the technology would appear to dominate - it is more effective and less costly to the NHS, but it should be rejected nevertheless due to wider consumption costs. For example, net consumption costs may be substantial due to the future health and non health care costs of a life saving intervention in populations where the remaining life cycle consumption exceeds the value of production, e.g., in older populations.[2]

Net consumption benefits ($\Delta c_c < 0$ **)**

When there are net consumption benefits for the wider economy there is an unambiguously negative bias against the technology. The simple decision rule neglects the benefits falling on the wider economy and there is a danger that the technology will be rejected when it should be approved. For example, if $\Delta c_h = £30,000$ and $\Delta c_c = -£60,000$ then the true net health benefit would be:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£30,000}{£20,000}\right] - \frac{-£60,000}{£60,000} = 0.5$$

and it should be approved. The net health benefit would be underestimated using (1),

$$\Delta h - \frac{\Delta c_h}{k} = 1 - \frac{£30,000}{£20,000} = -0.5$$

and the technology would be wrongly rejected. Again, the size of the bias will be greater when the net consumption benefit is larger and when the consumption value of health is lower.

If the technology also saves NHS resources there will still be a bias against the technology but this bias will not effect the decision as the technology would dominate and be approved anyway using the simple decision rule in (1). However, it should be noted that even when the bias does not or cannot effect the decision to approve or reject a technology any bias in the estimate of net health benefit will affect estimates of uncertainty and the potential value of additional evidence.

When the technology is less effective ($\Delta h < 0$)
It should also be recognised that once a wider perspective is adopted then any net consumption benefits must necessarily be traded with net health benefit within the health care sector. This means that a technology which is less effective $\Delta h = -1$ and more costly to the NHS $\Delta c_h = £10,000$, which would normally be dismissed as not cost-effective, may become worthwhile and should be approved if the net consumption benefits are sufficiently large ($\Delta c_c = -£120,000$). In this case,

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[-1 - \frac{£10,000}{£20,000}\right] - \frac{-£120,000}{£60,000} = 0.5$$

and the technology should be approved despite being less effective and more costly. For example, as above, a less effective treatment (in terms of survival) in older populations where remaining life cycle consumption exceeds the value of production may be approved even if it is more costly to the NHS. The potential implications of adopting a coherent wider perspective for the social consensus which underpins NICE the objectives of the Department of Health and the NHS itself are discussed in Section 3.3.

B Treat net consumption costs as if they fall on the budget constraint

This is a characterisation of the position of some consultees and appellants during a number of NICE Technology Appraisals including the applicants during Judicial review in 2007. It represents a rather naive view that all costs should be included but decisions should still be based on comparing the resulting ICER with the current threshold, i.e.,

$$\frac{\Delta c_h + \Delta c_c}{\Delta h} < k$$

which can be expressed in terms of net health benefit:

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{k} > 0 \qquad (8)$$

The difference between (8) and (5) is equal to a bias of,

$$\frac{\Delta c_c}{v} - \frac{\Delta c_c}{k} \qquad (9)$$

This bias depends on the value of Δc_c and the relative values of v and k. It should be apparent that when $v = k$, so the budget for health care is 'optimal' with respect to the social welfare function implied by v, there will be no bias - all costs could be regarded as if they fall on the constraint (recall in this section we assume that all costs are marginal to the budget so no transfers are required). However, there is no reason to believe that budgets are set optimally with respect to the type of welfare functions which are used to derive or are implied by currently proposed values for v. In addition, the evidence for estimates of k and the estimates of v proposed, suggest that as assumed here, $v > k$ (see Section 3.1).

Net consumption costs **(** $\Delta c_c > 0$ **)**

Given that $v > k$ there is an unambiguous negative bias against the technology when there are net costs imposed on the wider economy. The use of simple decision rule in (8) wrongly assumes that wider costs displace health (at a rate of k) when in fact they only displace consumption (valued at $\frac{1}{v}$), i.e., it overestimates the importance of net consumption costs. For example, if $\Delta h = 1$, $\Delta c_h = £5,000$ and $\Delta c_c = £30,000$ then the true net health benefit would be:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£5,000}{£20,000}\right] - \frac{£30,000}{£60,000} = 0.25,$$

and it should be approved. However, the net health benefit would be underestimated using the decision rule in (8),

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{k} = 1 - \frac{£5,000 + £30,000}{£20,000} = -0.75$$

and a technology would be wrongly rejected. Clearly, the size of this bias and the danger of a wrong decision will be greater when the consumption costs are larger and when the difference between v and k is greater. If a technology saves NHS resources ($\Delta c_h < 0$) the negative bias still remains. The true opportunity costs will be overestimated and net health benefit underestimated using the decision rule in (8). Again a technology could be wrongly rejected.

Net consumption benefits **(** $\Delta c_c < 0$ **)**

When there are net consumption benefits for the wider economy ($\Delta c_c < 0$**)** there is an unambiguously positive bias in favour of the technology. The simple decision rule in (8) treats the wider cost savings as if they accrue to the NHS which can be used to generate health at rate k. The importance of consumption benefits are overestimated and there is a danger that the technology will be approved when it should be rejected. For example, if $\Delta c_h = £40,000$ and $\Delta c_c = -£30,000$ then the true net health benefit would be:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£40,000}{£20,000}\right] - \frac{-£30,000}{£60,000} = -0.5,$$

and it should be rejected. However, the net health benefit would be overestimated using the decision rule in (8),

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{k} = 1 - \frac{£40,000 - £30,000}{£20,000} = 0.5$$

and a technology would be wrongly approved. If the technology also saves NHS resources it would dominate and be approved using the simple decision rule in (8), but there will still be a bias in favour of the technology but this bias will not effect the decision. As previously, it should be noted that even when the bias does not effect the decision, any bias in the estimate of net health benefit will affect estimates of uncertainty and the potential value of additional evidence.

C Ignore the budget constraint

This represents the greater part of literature on evaluation outside health (cost-benefit analysis), where the fact of exogenous constraints and the implications for opportunity costs are rarely acknowledged and even less commonly dealt with analytically. It also represents the implicit view of those who argue that the cost-effectiveness threshold should reflect some social consumption value of health (v) rather than what is forgone in a budget constrained system (k). This can be described as comparing the ICER which includes all costs falling on all sectors with a social consumption value of health, i.e.,

$$\frac{\Delta c_h + \Delta c_c}{\Delta h} < v$$

This can be expressed in terms of net health benefit:

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{v} > 0 \qquad (10)$$

The difference between (10) and (5) is equal to a bias of,

$$\frac{\Delta c_h}{k} - \frac{\Delta c_h}{v} \qquad (11)$$

Unlike the two other simple decision rules this bias depends on the value of Δc_h, not Δc_c. Therefore, it is whether the additional NHS costs are positive or negative that matters rather then whether there are net costs or net benefit to the wider economy. The bias also depends on relative values of v and k but in a different way than previously. If, as assumed throughout, $v > k$, the bias will always be positive for technologies with positive incremental NHS costs ($\Delta c_h > 0$) and negative for those that are cost saving to the NHS ($\Delta c_h < 0$). The reason, is that any additional health care costs are assumed to fall on consumption rather than lead to health forgone (at rate k). Therefore, the true value of health care costs (the health forgone) is underestimated and there will be a bias in favour of the technology. For example, if $\Delta c_h = £60,000$ and $\Delta c_c = -£30,000$ then the true net health benefit would be:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£60,000}{£20,000}\right] - \frac{-£30,000}{£60,000} = -1.5$$

and the technology should be rejected. However, the net health benefit will be overestimated if the simple decision rule in (10) is used,

$$\Delta h - \frac{\Delta c_h + \Delta c_v}{v} = 1 - \frac{£60,000 - £30,000}{£60,000} = 0.5$$

and a technology which should be rejected would be approved. Where the technology saves NHS resources there will be a bias against the technology because the value of the resource saving should be the health that can be gained from them rather than consumption saved. If there are also wider benefits ($\Delta c_c < 0$) then this bias will not effect the decision. However, if there are wider consumption costs ($\Delta c_c > 0$) then it is possible that a technology that should be accepted would be rejected using the simple decision rule in (10).

Summary of potential biases

It seems clear that, even when changes are marginal, all the simple decision rules which characterise a number of policy options create biases in different directions. In many common circumstances these biases could lead to false positive decisions, where a technology that should be rejected is wrongly approved, or false negative decisions where a technology that should be approved is wrongly rejected. The direction of bias and the potential for false positive (FP) of false negative (FN) decisions is summarised in Table III.

It should be emphasised that even when the potential bias cannot lead to an FP or FN decision, because the technology will always dominate or be dominated (D), the bias in the estimates of net health benefit will also lead to bias any assessment of uncertainty and the value of evidence. It should also be noted that accounting for wider effects outside the health care budget necessarily requires a trade-off to be made between health benefits in the health sector and net consumption costs in the wider economy. One implication is that a technology which is less effective and more costly to the NHS would be approved if there are sufficiently large net consumption benefits. Similarly a technology which is more effective and less costly to the NHS may be rejected due to net consumption costs. For example, technologies which have an effect on mortality in older populations where the remaining life cycle consumption exceeds the value of production may generate large external net costs if it was effective but large external net benefits if it was less effective than other therapies. Of course, the relative value of interventions which improve quality of life rather than life expectancy would be improved in these populations.[2]

Table III Bias and potential for decision error (marginal changes)

	A. Ignore wider costs		B. Costs on budget		C. Ignore constraint	
Type of Technology	**Bias**	**Decision**	**Bias**	**Decision**	**Bias**	**Decision**
More effective						
Net consumption costs						
Positive costs (NHS)	+	FP	-	FN	+	FP
Cost saving (NHS)	+	FP	-	FN	-	FN
Net consumption benefits						
Positive costs (NHS)	-	FN	+	FP	+	FP
Cost saving (NHS)	-	D	+	D	-	D
Less effective						
Net consumption costs						
Positive costs (NHS)	+	D	-	D	+	D
Cost saving (NHS)	+	FP	-	FN	-	FN
Net consumption benefits						
Positive costs (NHS)	-	FN	+	FP	+	FP
Cost saving (NHS)	-	FN	+	FP	-	FN

The potential bias associated with these three polices can also be illustrated graphically. The bias associated with each is illustrated in Figure 1 for net consumption costs (Δc_c) ranging from -£100,000 to £100,000.

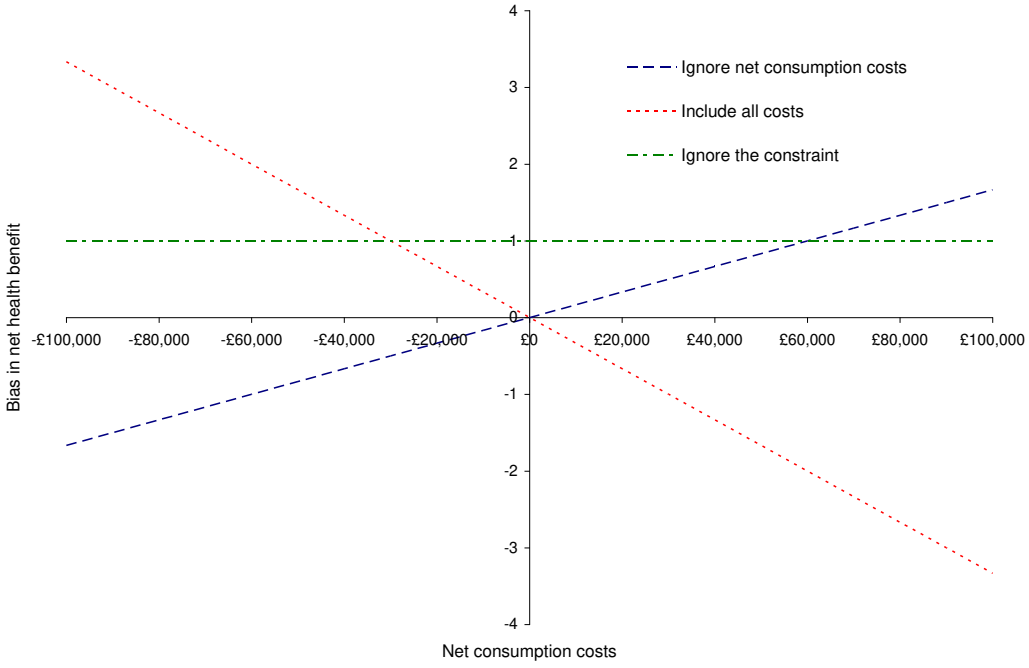

Figure 1. Potential bias for different values of Δc_c

$(k = £20,000,\ v = £60,000,\ \Delta h = 1,\ \Delta c_h = £30,000)$

Figure 1 illustrates that the bias associated with either ignoring Δc_c or treating it as if it falls in the budget for health care are always opposite, i.e., when one overestimates the other underestimates. The only point at which neither is biased is when $\Delta c_c = 0$. It also illustrates that the bias introduced by ignoring the constraint is independent of Δc_c. In this case there is a positive bias because Δc_h is positive in this example.

Figure 2 illustrates the biases for different net health care costs which fall on the budget (Δc_h) ranging from -£100,000 to £100,000. It illustrates that the bias of ignoring the constraint depends on whether Δc_h is positive or negative, with the size of the positive (negative) bias increasing (decreasing) with Δc_h. The bias associated with the other two simple decision rules is independent of Δc_h. In this example ignoring the wider net consumption costs introduces a positive bias as Δc_c is positive in this example.

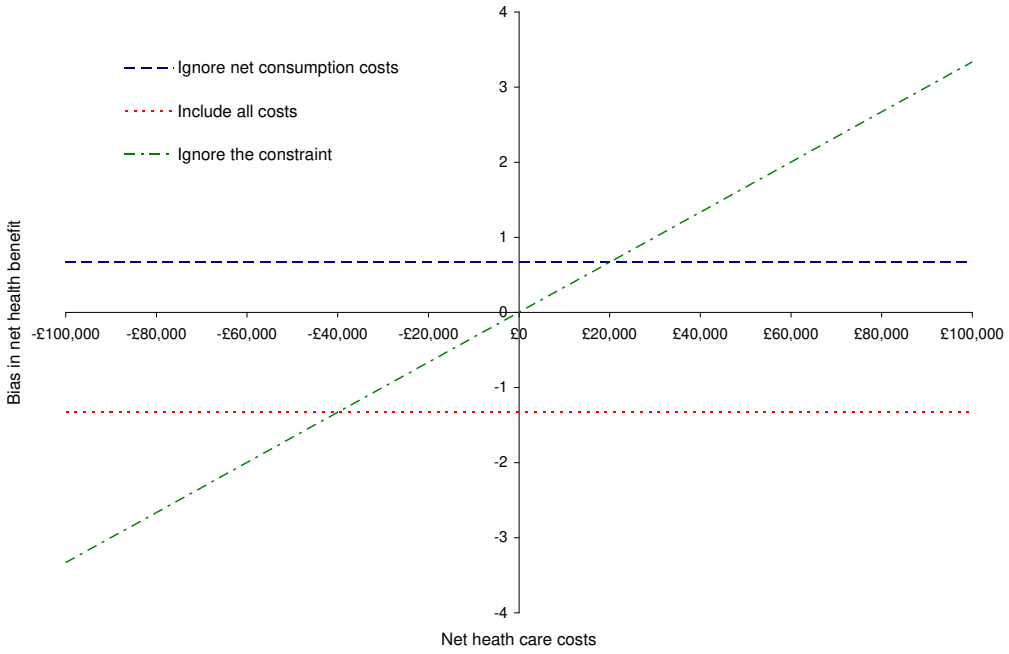

Figure 2. Potential bias for different values of Δc_h

(Δc_h $k = £20,000$, $v = £60,000$, $\Delta h = 1$, $\Delta c_c = £40,000$)

The relationship between the potential bias and an estimate of the consumption value of health is illustrated in Figure 3 where the cost-effectiveness threshold is £20,000 per unit of health gained. It illustrates that ignoring the constraint or treating wider costs as if they fall on the budget will not lead to any bias if the budget is set optimally with respect to the value of v and the welfare function it presupposes ($v = k$). Recall, we are still assuming that changes are marginal, i.e., are small relative to the budget so that v and k do not change. However, there is little reason to suppose that budgets are set in this way and good reasons to believe that ($v > k$). As v becomes much greater than k, the bias associated with ignoring wider consumption costs falls because the weight that should be attached to them falls. However, the bias associated with either ignoring the constraint or treating wider costs as if they fall on the budget increases. Therefore, in assessing the potential biases of alternative policies an important consideration is the relative values of v and k assuming one is willing to specify an explicit value of v for these purposes.

Understanding the bias introduced by incomplete decision rules which characterise some of the policy options is instructive, but it poses the question of why consider adopting simple but incomplete policies when the appropriate decision rule in (5) is available? There are broadly two reasons why the decision rule described in (5) may not be appropriate or feasible and when the other simple but incomplete rules might lead to better outcomes. Firstly, it has been assumed that all changes are marginal. But even if individual decisions might be considered marginal in isolation, the repeated application of the decision rule will lead to non marginal changes. If transfers are not possible then the implied reallocation of resource between sectors may not be socially desirable, particularly if an explicit welfare function cannot be completely specified. The implications of non marginal changes are dealt with in Section 2.3. Secondly, adopting a particular value of v as used in (5) implies a particular and simple welfare function which is unlikely to capture all arguments of social value and may conflict with other agreed social objectives. Indeed any particular welfare function is unlikely to carry consensus or social legitimacy. The difficulty and implications of being unable to specify an explicit welfare function is dealt with later in Section 3.1.

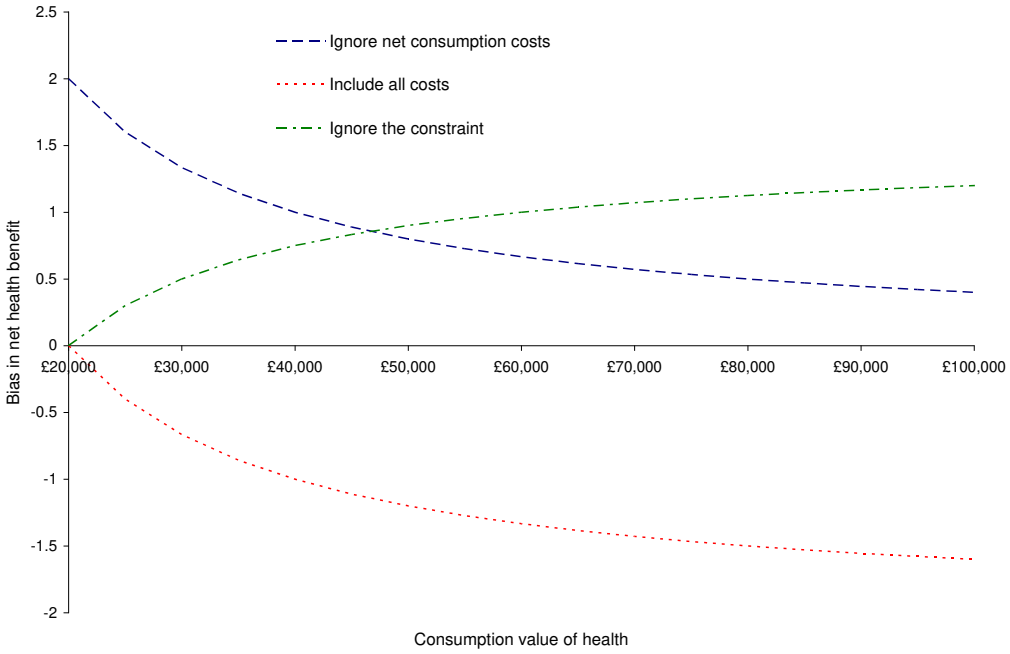

Figure 3. Potential bias for different values of v
($k = £20,000$, $\Delta h = 1$, $\Delta c_h = £40,000$, $\Delta c_c = £40,000$)

2.3 Non marginal changes

It has been assumed in previous sections that each decision, when considered in isolation, can be regarded as having a marginal impact on either the budget of the health care system or on the value of economic activity in the wider economy. However, even if the effect of individual decisions might be considered marginal, the repeated application of the decision rules described above to a sequence of decisions will ultimately lead to non marginal changes, i.e. a sufficient number of 'marginal' changes tending in the same direction will have non marginal effects. This poses a number of problems: i) a failure to account for non marginal effects will lead to a biased assessment of cost-effectiveness and an unambiguous increase in the possibility of false positive decisions; ii) even when non marginal effects are accounted for and bias is avoided, unless transfers are made to compensate for non marginal effects then the implied reallocation of resource between sectors may not be socially desirable, particularly if an explicit welfare function cannot be completely specified; and iii) the informational requirements to fully account for non marginal effects are generally not achievable so this cannot represent a realistic or feasible policy option. However, it does provide the appropriate bench mark against which to judge the potential biases of those policies which are possible.

The effect of a non marginal impact on the health care budget means that the additional total health care costs displace not just the marginal NHS activities but other more productive activities. The health forgone is not given by k but by some lower threshold $k^* < k$ that represents the greater health forgone as both marginal and then less marginal activities are displaced. Even if a health technology saves health care resources ($\Delta c_h < 0$), and this saving is non marginal with respect to the budget, the health that is gained by using saved resources to engage in other activities will be overestimated unless account is taken of the diminishing productivity of additional activities which can be funded, i.e., less health is produced from the resources saved and $k^* > k$.

Total health care costs will depend on the per patient incremental cost (Δc_h) and the size of the eligible patient population. Whether these costs should be regarded as marginal or not depends on their size relative to the budget for health care (or at least that part of the budget devoted to discretionary activities which could be displaced to accommodate the additional costs) and how fast the marginal productivity of the health care system is falling, i.e. whether health care is more or less productive of health. For example, a total cost representing the same proportion of the available budget could be regarded as marginal if the health care system is less productive ('flat of the curve medicine') but non marginal if the health care system is more productive. Recent empirical evidence suggests that NHS is remarkably productive of health and very far from 'flat of the curve medicine'.[28] Therefore, the non marginal effects of a single decision or a series of decisions is likely to be more significant to the NHS.

In general non marginal effects of costs falling on the health care budget are likely to be more significant than consumption costs or benefits falling on the wider economy. The health care budget is only a fraction of the total value of economic activity so health care costs will tend to constitute a greater proportion of the budget compared to consumption costs and benefits which are likely to represent a relatively small proportion of the total value of economic activity. Also, there are currently no strong incentives or other reasons to suppose that new technologies will generally offer mainly consumption costs or mainly consumptions benefits as this will depend on the characteristics of the disease (e.g., chronic or acute), the effect of the technology (e.g., mortality or quality of life effect) and the patient population (e.g., older or younger). Therefore, even when changes are repeated there is no particular reason to believe they will tend to be in the same direction. However, the health care costs of new technologies will tend to be positive because there is an incentive for manufacturers to price products to be just cost-effective and, in doing so, they appropriate any other NHS resource savings offered by an effective technology in higher prices. Of course, the entry of generics tends to reduce prices and open the possibility of cost savings. However, there is also an incentive to launch new branded products before patent expiry and price them such that $\Delta c_h > 0$. Although there may be exceptions, across the technologies offered to the NHS the health care costs will generally be positive. This expectation is borne out over the last 10 years of NICE Technology Appraisals. Therefore, a series of apparently marginal changes in health care costs will tend to be in the same direction so will ultimately have non marginal effects.

It seems reasonable then to assume that effects on the wider economy will be marginal (i.e., that any net consumption costs imposed on the economy will not reduce the consumption value of health and that net consumption benefits will not increase it), or at least 'more marginal' than the costs which fall on the health care budget. Throughout the following section it is assumed for ease of exposition that consumption costs and benefits will be marginal with respect to the economy (v is constant) but that health care costs or savings may have non marginal effects ($k^* < k$ if $\Delta c_h > 0$ and $k^* > k$ if $\Delta c_h < 0$). As well as being a reasonable simplifying assumption the insights are generalisable as long as the effects on the wider economy tend to be 'more marginal' than those on the health care system.

The general case with full information (k^* is known)

The allocation decision can be expressed in terms of net health benefit in a very similar way to the marginal changes described in (5) above:

$$\left[\Delta h - \frac{\Delta c_h}{k^*}\right] - \frac{\Delta c_c}{v} > 0 \qquad (12)$$

As previously, the decision can be described as a comparison of the net health gained in the health sector (1st term) with the health equivalent of the net consumption costs falling on the wider economy (2nd term). If the former exceed the latter then the technology should be adopted. The difference is that the additional costs falling on the budget ($\Delta c_h > 0$) displace not just the marginal NHS activities but other more productive activities so that the heath forgone is not given by k but by $k^* < k$.

For example, an effective ($\Delta h = 1$) but more costly ($\Delta c_h = £19,000$) health technology, would, if approved, be made available to 10,000 patients. Therefore, the total costs of approval would be £190 million falling on the budget constraint. These additional costs may displace many other productive activities so the health forgone will not be given by the original threshold $k = £20,000$ but will be greater, i.e., a lower threshold of $k^* = £18,500$. Initially assuming that there are no net consumption costs or benefits ($\Delta c_c = 0$), then:

$$\left[\Delta h - \frac{\Delta c_h}{k^*}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£19,000}{£18,500}\right] = -0.027$$

The technology should be rejected even though the $ICER = £19,000$ is less than the initial threshold of £20,000 because the costs imposed on the budget are non marginal and displace more health – the threshold falls to k^*. Using the decision rule for marginal changes described in (5) above would overestimate cost-effectiveness:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£19,000}{£20,000}\right] = 0.05$$

and a technology which should be rejected would be wrongly accepted.

The general case with partial information (k^* is unknown)

The extent to which cost-effectiveness will be overestimated by assuming a change is marginal when in fact it is not can be expressed in health terms as the difference between (5) and (12),

$$\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k} \qquad (13)$$

This represents the potential bias of basing decisions on an estimate of k when in fact the change is non marginal and requires an estimate of k^*. This bias will always be positive, i.e., cost–effectiveness will be unambiguously over estimated. The size of this bias will depend on the total health care costs (Δc_h and the eligible patient population) and how 'non marginal' these total costs are (the difference between k and k^*). Of course, the latter is also related to the former: if Δc_h and/or the eligible population is larger, more non marginal activities will be displaced and the difference between k and k^* will tend to be greater. In circumstances when the technology saves health care resources ($\Delta c_h < 0$), and these savings are non marginal with respect to the budget, the health that is gained by using saved resources to engage in other activities is not given by k but by $k^* > k$. The bias will also be positive and the cost-effectiveness will be overestimated using the marginal decision rule that fails to account for the diminishing productivity of additional activities which can be funded, i.e., less health is produced from the resources saved and cost saving treatments will appear more desirable than they really are.

This problem of non marginal impacts of Δc_h on the budget arises whether or not there are external effects on the wider economy. However, it is important to recognise that when there are external net consumption benefits then greater non marginal impacts on the budget are likely (see discussion of dynamic effects in Section 3.3), and any particular impact more likely to be wrongly approved if the decision rule for marginal changes is used. This means the consequences of making the wrong decision will tend to be greater. For example, if there were net consumption benefits of $\Delta c_c = -£66,000$ associated with the technology in the previous example then even if the technology

had much greater costs falling on the health care budget ($\Delta c_h = £40,000$) it would still be regarded as cost-effective if it was wrongly assumed that these costs are marginal and the original threshold of $k = £20,000$ was appropriate.

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£40,000}{£20,000}\right] - \frac{-£66,000}{£60,000} = 0.1$$

However, if this technology was approved and made available to the 10,000 patients the total costs falling on the budget would more than double to £400 million, displacing even more productive activities. The appropriate threshold for this significantly greater change will be even lower than previously (for example, $k^* = £16,000$ rather than £18,500).

$$\left[\Delta h - \frac{\Delta c_h}{k^*}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£40,000}{£16,000}\right] - \frac{-£66,000}{£60,000} = -0.4$$

This technology, which appeared cost-effective when the impact was assumed to be marginal, should in fact be rejected. Importantly, taking account of the net consumption benefits while assuming that the greater health care costs are marginal leads to a much larger bias (0.5 compared to 0.077) and an even worse decision. In both examples the wrong decision is made but, in this case, the consequences of making the wrong decision are greater for the public health – a loss of 0.4 QALYs per patient treated compared to 0.027, or 4,000 QALYs lost for the patient population compared to 270 previously.

The problem arises from basing decisions on an estimate of k when in fact the change is non marginal and requires an estimate of k^*. The difficulty is that even when the impact on the budget of a single decision or a sequence of decisions is known to be non marginal, establishing an appropriate estimate of k^* for each decision is not going to be possible. In principle, establishing an appropriate estimate of k at a particular historic point in time is possible[28] and the direction of the change due to non marginal impacts is also predictable ($k > k^* \; if \; \Delta c_h > 0$). However, establishing the magnitude of this effect is much more difficult for two reasons: i) the information requirements about the performance of the health care system to establish k^* for each Δc_h and for each decision in a sequence is currently not achievable[b]; and ii) it would require a different cost-effectiveness threshold for every decision which would also change over time - it would depend not only on Δc_h and the eligible population but also on where in the sequence the decision happened to fall. This would offer an uncertain, unpredictable and ever-changing target for investment decisions in health technologies. Therefore, in the face of the fundamental difficulty posed by the informational requirements, current NICE policy can be viewed as establishing a value for k which is periodically reviewed and revised if necessary in the knowledge that it will be an increasingly poor approximation, and where significant budget impact is 'taken into account' in a deliberative way. Therefore, although improved estimates of k and a better understanding of the effect of non marginal budget impacts will be possible, fully accounting for every non marginal impact using the decision rule in (12) will remain elusive so it can not represent a realistic or feasible policy option. However, it does provide the appropriate benchmark against which to judge the potential biases of those policies which are possible.

This is a familiar and general problem in economics where second best rules (in this case fully accounting for non marginal changes in (12)) in a second best world (one of non marginal changes) are impossible to formulate due to the informational requirements, but the application of first best rules (assuming there are only marginal changes (5)) in a second best world may make matters worse. The task is to find feasible third best rules (approximations) which may perform better in a

[b] Recently commissioned research which exploits national data to estimate the threshold may also provide an indication of the effect of non marginal budget impacts. However, even if such estimates prove to be possible and robust they will necessarily be historic the second best decision rule in (12) will remain elusive.

second best world. Therefore, it is worth re-examining the three simple but incomplete decision rules considered previously in the context of non marginal changes.

A Ignore effects outside the health sector

This characterisation of current NICE policy can be expressed as a decision rule based on net health benefit, given in (1) above and repeated here,

$$\Delta h - \frac{\Delta c_h}{k} > 0$$

Any net consumption costs or benefits are ignored and the difference between (1) and (12) is equal to the bias of,

$$\left[\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}\right] + \frac{\Delta c_c}{v} \qquad (14)$$

Notice that the second term is the same as previously when only marginal changes where considered (see (7) above) and reflects that any net consumption effects falling on the wider economy are neglected, i.e., if there are net consumption costs ($\Delta c_c > 0$) there will be a positive bias and cost-effectiveness will be overestimated, but if there are net consumption benefits ($\Delta c_c < 0$), which are not accounted for, cost-effectiveness will be underestimated (the bias is negative). The first term is the same as (13) and represents the effect of failing to account for the non marginal effect of health care costs, i.e., there will be an unambiguous positive bias in favour of the technology as the decision fails to take account of the additional forgone health as more productive non marginal activities are displaced. Therefore, there are two sources of bias which work in the same direction (positive bias) when there are net consumption costs, but tend to offset each other when there are net consumption benefits.

Net consumption costs **($\Delta c_c > 0$)**

When there are net consumption costs falling on the wider economy and also positive costs falling on the health care system, both sources of bias work in the same direction leading to an unambiguous positive bias. For example, if $\Delta h = 1$, $\Delta c_c = £60,000$ and the additional health care costs of $\Delta c_h = £20,000$ imply a non marginal change so that a lower threshold of $k^* = £16,000$ would be appropriate rather than the original threshold $k = £20,000$, then,

$$\left[\Delta h - \frac{\Delta c_h}{k^*}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£20,000}{£16,000}\right] - \frac{£60,000}{£60,000} = -1.25$$

The technology should be rejected when the additional wider costs and the lower threshold due to non marginal effects have been taken into account. The simple decision rule which ignores both will overestimate cost-effectiveness,

$$\Delta h - \frac{\Delta c_h}{k} = 1 - \frac{£20,000}{£20,000} = 0$$

In this case the technology may be wrongly accepted (the $ICER = k$ and it wrongly appears just acceptable).

Net consumption benefits **(** $\Delta c_c < 0$ **)**

When there are net consumption benefits accruing to the wider economy both sources of bias work in the opposite direction and tend to off set each other. For example if $\Delta c_c = -£15,000$ rather than £60,000 above,

$$\left[\Delta h - \frac{\Delta c_h}{k^*}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£20,000}{£16,000}\right] - \frac{-£15,000}{£60,000} = 0$$

The technology would be just acceptable: the health and the health equivalent of consumption expected to be gained is just offset by the health forgone. The simple decision rule leads to the same assessment of cost-effectiveness,

$$\Delta h - \frac{\Delta c_h}{k} = 1 - \frac{£20,000}{£20,000} = 0$$

So, in this example, there is no net bias. The negative bias from ignoring wider benefits $\left(\frac{\Delta c_c}{v}\right)$ is just offset by the positive bias of failing to account for displacing more productive non marginal activities $\left[\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}\right]$. Therefore, when there are net consumption benefits combined with non marginal health care costs, this simple decision rule may under or overestimate cost-effectiveness depending on the relative effect of these two sources of bias. Clearly, it is more likely to overestimate cost-effectiveness if total health care costs are greater (a larger population and/or greater Δc_h) but less likely if consumption benefits are greater.

B Treat net consumption costs as if they fall on the budget constraint

This represents the rather naive view that all costs should be included but decisions should still be based on comparing the resulting ICER with the current threshold which can be expressed in terms of net health benefit given in (8) above and repeated here,

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{k} > 0$$

The difference between (8) and (12) is equal to a bias of,

$$\left[\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}\right] + \left[\frac{\Delta c_c}{v} - \frac{\Delta c_c}{k}\right] \qquad (15)$$

Notice again that the second term is the same as previously when only marginal changes where considered (see (8) above). Given that $v > k$ there is a negative bias against the technology when $\Delta c_c > 0$ because it wrongly assumes that wider costs displace health (at a rate of k) when in fact they only displace consumption (valued at $\frac{1}{v}$), i.e., the importance of net consumption costs are overestimated. When $\Delta c_c < 0$ there is a positive bias in favour of the technology because wider cost savings are wrongly treated as if they accrue to the NHS and can be used to generate health at

rate k , i.e., the importance of consumption benefits are overestimated. Again, the first term is the same as (13) and represents the effect of failing to account for the non marginal effect of health care costs, and offers an unambiguous positive bias in favour of the technology if total health care costs or cost savings are non marginal. Therefore, there are two sources of bias which tend to offset each other when there are net consumption costs but work in the same direction (a positive bias) when there are net consumption benefits.

Net consumption costs **(** $\Delta c_c > 0$ **)**

When there are net consumption costs falling on the wider economy and also positive costs falling on the health care system, both sources of bias work in the opposite direction and tend to offset each other. For example, if $\Delta h = 1$, $\Delta c_c = £6,000$, and the additional health care costs of $\Delta c_h = £12,000$ imply a non marginal change so that a lower threshold of $k^* = £16,000$ rather than $k = £20,000$ would be appropriate, then,

$$\left[\Delta h - \frac{\Delta c_h}{k^*}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£12,000}{£16,000}\right] - \frac{£6,000}{£60,000} = 0.15$$

The technology should be accepted when the net consumption costs and the lower threshold due to non marginal effects have been taken into account. The simple decision rule which over values Δc_c but under values Δc_h leads to a similar assessment of cost-effectiveness,

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{k} = 1 - \frac{£12,000 + £6,000}{£20,000} = 0.1$$

The same decision to accept the technology would be made because, in this case, the negative bias from imagining that Δc_c displaces health offsets the positive bias of failing to account for Δc_h displacing more productive non marginal activities.

Net consumption benefits ($\Delta c_c < 0$ ***)***

When there are net consumption benefits accruing to the wider economy both sources of bias work in the same positive direction. For example if $\Delta c_c = -£6,000$ and $\Delta c_h = £18,000$ then,

$$\left[\Delta h - \frac{\Delta c_h}{k^*}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£20,000}{£16,000}\right] - \frac{-£6,000}{£60,000} = -0.15$$

and the technology should be rejected. However, using the simple decision rule in (8) which overvalues the consumption benefits and under values health care costs,

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{k} = 1 - \frac{£20,000 - £6,000}{£20,000} = 0.7$$

cost-effectiveness is seriously overestimated and the technology would be wrongly approved.

C Ignore the budget constraint

This represents the greater part of literature on evaluation outside health where the fact of exogenous constraints and the implication for opportunity costs are rarely acknowledged. It can be described as comparing the ICER, which includes all costs falling on all sectors, with a social consumption value of health which can be expressed in terms of net health benefit given in (10) above and repeated here:

$$\Delta h - \frac{\Delta c_h + \Delta c_c}{v} > 0$$

The difference between (10) and (12) is equal to a bias of:

$$\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{v} \qquad (16)$$

This appears to be very similar to the bias associated with marginal changes (see (11) in 2.2) which showed that the bias depends only on the value of Δc_h, not Δc_c. In fact, the only difference is the denominator of the first term which is now k^* rather than k. Given that $v > k$, the bias will always be positive for technologies with positive incremental NHS costs ($\Delta c_h > 0$). However, this bias will be greater if total costs are greater (more non marginal) because k^* will tend to be lower (more health is forgone). Therefore, the effects of failing to recognise both the health opportunity cost of $\Delta c_h > 0$ and the non marginal nature of such costs will work in the same direction (a larger positive bias). Using the same example as in Section 2.2, where $\Delta c_c = -£30,000$ but $\Delta c_h = £60,000$ is non marginal so $k^* = £16,000$ is needed rather than $k = £20,000$, the true net health benefit would be:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \frac{\Delta c_c}{v} = \left[1 - \frac{£60,000}{£16,000}\right] - \frac{-£30,000}{£60,000} = -2.25$$

and the technology should be rejected. However, the net health benefit will be overestimated if the simple decision rule in (10) is used,

$$\Delta h - \frac{\Delta c_h + \Delta c_v}{v} = 1 - \frac{£60,000 - £30,000}{£60,000} = 0.5$$

and a technology which should be rejected would be approved. The positive bias when the change is non marginal is greater than when the same change is regarded as marginal in 2.2 (a bias of 2.75 compared to 2).

If a technology saves NHS resources ($\Delta c_h < 0$), the bias will be negative because (10) fails to account for the health that could be generated from the additional NHS activities. If these cost savings are non marginal then $k^* > k$ because the productivity of additional activities will tend to decline. Therefore, the effects of failing to recognise the health gained from costs savings will be somewhat off set by failing to recognise the effects of a non marginal saving. The net bias will be unambiguously negative but less so than assuming the change was marginal (as in 2.2 above).

Summary of potential biases

The non marginal decision rule in (12) does not represent a realistic or feasible policy option due to informational requirements which are very unlikely to be achieved. However, it does provide the appropriate benchmark against which to judge the potential biases of those policies which are possible. The task is to find feasible third best rules (approximations) which may perform better in a second best world (where changes are ultimately non marginal). In particular, it is important to ask whether the use of a first best rule (assuming changes are marginal (5)) in a second best world may make matters worse.

When changes are non marginal and no transfers are possible, all the decision rules which characterise a number of possible policy options (third best rules) create biases in different ways to when changes were regarded as marginal (see Table III in Section 2.2). The direction of bias and the

potential for false positive (FP) of false negative (FN) decisions is summarised in Table IV which also includes the bias and potential error associated with using the decision rule for marginal changes (5) when they are non marginal.

Table IV Bias and potential for decision error (non marginal changes)

Type of Technology	A. Ignore wider costs		B. Costs on budget		C. Ignore constraint		D. Marginal rule (5)	
	Bias	Decision	Bias	Decision	Bias	Decision	Bias	Decision
More effective								
Net consumption costs								
Positive costs (NHS)	+	FP	-/+	FN/FP	+	FP	+	FP
Cost saving (NHS)	+	FP	-/+	FN/FP	-	FN	+	FP
Net consumption benefits								
Positive costs (NHS)	-/+	FN/FP	+	FP	+	FP	+	FP
Cost saving (NHS)	-/+	D	+	D	-	D	+	D
Less effective								
Net consumption costs								
Positive costs (NHS)	+	D	-/+	D	+	D	+	D
Cost saving (NHS)	+	FP	-/+	FN/FP	-	FN	+	FP
Net consumption benefits								
Positive costs (NHS)	-/+	FN/FP	+	FP	+	FP	+	FP
Cost saving (NHS)	-/+	FN/FP	+	FP	-	FN	+	FP

A few things are apparent:

i) Regarding changes as marginal when they are not, always leads to a positive bias and increases the danger of false positive decisions unless the decision is fully dominated (e.g., the technology is more effective, cost saving to the NHS and offers net consumption benefits).

ii) The effect of this additional positive bias (even if budgets are regarded as optimal) is to accentuate any positive bias associated with marginal changes (see Table III). It also means that ignoring wider effects when these are wider benefits but treating any external costs as if they fall on the budget might offset the positive bias associated with non marginal changes leading to a less biased assessment of cost-effectiveness in some circumstances. The pattern of bias from ignoring the constraint remains as before but any positive bias will be greater and any negative bias will tend to be less.

iii) Overall, once the non marginal nature of a single decision or a sequence of decisions is acknowledged, it becomes apparent that there is generally an increased risk of making false positive decisions – accepting a technology that should be rejected.

No single policy is necessarily unbiased in any of the possible circumstances described in Table IV (even if the budget is regarded as optimal). However, it maybe that some are less biased than others. The bias associated with each is summarised in Table V.

Table V. Bias associated with decision rules

	Size of bias
A. Ignore wider costs	$\left[\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}\right] + \frac{\Delta c_c}{v}$
B. Costs on budget	$\left[\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}\right] + \left[\frac{\Delta c_c}{v} - \frac{\Delta c_c}{k}\right]$
C. Ignore constraint	$\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{v}$
D. Marginal rule (5)	$\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}$

Assuming that $v > k$, some general statements can be made about which decision rules are likely to be least biased across a range of possible circumstances and which never perform better than others and may be disregarded. The relative ranking of biases are summarised in Table VI.

Table VI. Extent of bias associated with decision rules

Type of Technology		Ranking of extent of bias
More effective	$\Delta h > 0$	
Net consumption costs	$\Delta c_c > 0$	
Positive costs (NHS)	$\Delta c_h > 0$	$D < A$, $D < B$, $D < C$ and $A < B$
Cost saving (NHS)	$\Delta c_h < 0$	$D < A$, $D < B$, $D < C$ and $A < B$
Net consumption benefits	$\Delta c_c < 0$	
Positive costs (NHS)	$\Delta c_h > 0$	$D < A$, $D < B$, $D < C$ and $A < B$
Cost saving (NHS)	$\Delta c_h < 0$	$D < A$, $D < B$, $D < C$ and $A < B$
Less effective	$\Delta h < 0$	
Net consumption costs	$\Delta c_c > 0$	
Positive costs (NHS)	$\Delta c_h > 0$	$D < A$, $D < B$, $D < C$ and $A < B$
Cost saving (NHS)	$\Delta c_h < 0$	$D < A$, $D < B$, $D < C$ and $A < B$
Net consumption benefits	$\Delta c_c < 0$	
Positive costs (NHS)	$\Delta c_h > 0$	$D < A$, $D < B$, $D < C$ and $A < C$
Cost saving (NHS)	$\Delta c_h < 0$	$D < A$, $D < B$, $D < C$ and $A < C$

These rankings assume that the difference between v and k is not trivial ($v > 2k$) and this difference is more significant than the impact of non marginal changes, i.e., $2 - \frac{k^*}{v} > \frac{k^*}{k}$. The ranking in parentheses indicates that they are more likely to hold when consumption cost or benefits are relatively large, health care costs relatively small and the non marginal impact on the budget is more limited (smaller difference between k and k^*). If these additional conditions do not hold (the non marginal impact is large relative to external effects) the ranking in parentheses will be reversed (see Appendix A for details of the conditions).

Although no single decision rule is unbiased or dominates all others it is possible to draw some general conclusions from the ranking of bias reported in Table IV:

i) Ignoring the budget constraint (policy C) is dominated because the marginal decision rule (policy D) always offers less potential bias in each possible circumstance.
ii) Whether or not the technology is more or less effective or has positive or negative NHS costs does not affect the extent of bias associated with any of the possible decision rules.
iii) If net consumption effects are expected to be large relative to health care costs and their non marginal impact, then the 1st best marginal rule (policy D) may offer the least bias when there are net consumption costs (D<A and (D<B)) and when there are net consumption benefits ((D<A) and D<B).
iv) However, if these conditions do not hold, so that health care costs and their non marginal impact are large relative to net consumption effects, then a combination of policies would minimise the potential bias, i.e., when there are net consumption costs policy B would be least biased (D<A but now B<D) but when there are net consumption benefits policy A would be least biased (in these circumstances A<D and D<B).

Therefore, a combination of policy options might minimise the potential for bias: i.e., a marginal first best rule (policy D) when non marginal effects are believed to be relatively small but combination of third best rules (policy A and B) when they are not.

Interestingly, policy D - applying decision rules as if changes are marginal - can be viewed as a formalisation of the previous policy of taking net consumption costs or benefits 'into account', i.e., they are not given the same weight as costs falling on the NHS budget (policy B) but neither were they given zero weight and ignored (policy A). This decision rule (see (5) and (6)) simply formalises this process by giving a weight of $\left(\frac{k}{v}\right)$ to net consumption costs and benefits. However, it should be noted that the application of this formal decision rule to a sequence of decisions will always overestimate cost-effectiveness and will run the increasing risk of false positive decisions, particularly for technologies that have large total cost implications relative to the budget, and especially when these are being offset by claims of net consumption benefits in the wider economy.

It is possible to recognise the bias associated with non marginal effects by applying other decision rules when the impact is believed to be large relative to the external effects. For example, when a technology offers net consumption benefits it might be better to ignore the wider benefits because the negative bias from ignoring the benefits will tend to offset the positive bias from the non marginal effect. Equally, if the technology imposes wider costs, then it might be better to treat these costs as if they fall on the NHS budget because the negative bias from treating the wider costs as if they fall on the NHS will tend to offset the positive bias from the non marginal effects. Such a policy would be more stringent than the current NICE policy of ignoring the costs as well as benefits outside the health care system. Nevertheless there would still remain a possibility that cost-effectiveness will be overestimated and false positive decisions will be made. However, this combination of policies would mitigate the dangers of non marginal impacts on the NHS. Their implementation by NICE and the criteria for when each should be applied would require some knowledge of the likely impact of non marginal changes on the NHS, i.e., how the cost-effectiveness threshold changes with budget impact. Of course, this combination of polices does not overcome other difficulties, including: the explicit specification of a welfare function with potential conflicts with other social objectives; the likely dynamic effects; and the difficulty of adequately estimating displaced consumption benefits (see Chapter 3).

The difficulties associated with non marginal changes only arise when transfers are not made between the wider economy and the health care system. Although the implementation of transfers would effectively hand decisions about public expenditure on health over to a body such as NICE, which only has a remit to making decisions about health technologies within existing budget constraints, it is important to consider the opportunity costs of failing to allow such transfers to take place, how in principle the transfers required could be identified, and how the transfers could be made both within the public sector (between budget constrained sectors) and between the public sector and the wider economy. The following section explores these issues before Section 3 draws together the implications for policy and the question of value and fact on which alternative policies rest.

2.4 Transfers between sectors

A health technology may offer consumption benefits or impose consumption costs on the wider economy. It may also impose costs or offer benefits to other budget constrained public sectors. Without the possibility of transfers, which would internalise these external costs and benefits, a technology which is not cost-effective from the perspective of the health care systems may be rejected despite offering significant benefits to other public and private sectors. However, transfers between public sectors and the wider economy might not be regarded as a feasible policy option for two reasons: i) it would, in part at least, transfer responsibility for public expenditure and its allocation to those bodies which make decisions about health technologies; and ii) establishing and implementing transfers associated with each technology may have substantial transactions costs. Nevertheless, it is instructive to consider how, in principle, the value of transfers could be identified and what the opportunity costs of failing to make transfers would be in a range of circumstances. These include situations when decisions are regarded as marginal or non marginal, and when transfers can be made between a single budget constrained sector and the wider economy or when there are a number of budget constrained sectors.

Any transfers between sectors would need to be made in money terms. Therefore, the net effects of a technology can be expressed in money terms as the net consumption value (see (4) in Section 2.1).

A technology should be accepted if the net health benefits to the health care system (the term in brackets), which are valued at the consumption value of health (v), exceed the net consumption effects on the wider economy (Δc_c):

$$v.\left[\Delta h - \frac{\Delta c_h}{k}\right] - \Delta c_c > 0 \qquad (4)$$

Decisions based only on the perspective of the health care system (ignoring any effects outside the health care system (see Policy A and (1) in Section 2.1) would be to accept the technology if the net health benefits (term in brackets) are positive.

When would transfers be useful?

Decisions based on (4) or (1) would be equivalent and transfers would not be necessary if: i) net health benefits are positive and there are also consumption benefits or ii) if net health benefits are negative and there are consumption costs. However, transfers might be required if net health benefits are negative but the technology offers consumption benefits, or if net health benefits are positive but it imposes net consumption costs on the wider economy. In each case we consider i) what transfer would be necessary and ii) whether such a transfer would be socially desirable.

Net consumption benefits $(\Delta c_c < 0)$

If net health benefits are negative the technology may be accepted if the consumption benefits ($\Delta c_c < 0$) to the wider economy are greater than the consumption value of the net health benefits forgone. For example, if $\Delta h = 1$, $\Delta c_h = £30,000$ and $\Delta c_c = -£60,000$ then:

$$v.\left[\Delta h - \frac{\Delta c_h}{k}\right] > \Delta c_c, \quad £60,000\left[1 - \frac{£30,000}{£20,000}\right] = -£30,000 > -£60,000$$

The consumption benefits exceed the consumption value of net health benefits forgone and the technology offers a net consumption value of £30,000 per patient. However, such a technology would be rejected from a health care system perspective (net health benefit = -0.5). The question is how much transfer (T) of the consumption benefit from the wider economy would need to be made so that the technology would be regarded as just cost-effective from the perspective of the health care system, i.e., so the net health benefits, including the transfer, are at least zero:

$$\Delta h - \frac{\Delta c_h}{k} + \frac{T}{k} \geq 0 \qquad (17)$$

Therefore, the minimum transfer required from the wider economy to the health care system would need to be:

$$T \geq k\left[\frac{\Delta c_h}{k} - \Delta h\right], \quad T \geq £20,000\left[\frac{£30,000}{£20,000} - 1\right] = £10,000$$

The transfer must be at least equal to the resources required within the health care system to generate enough health elsewhere to just offset the net health benefits that will be forgone as a consequences of adopting the technology.

Therefore, transfers can be regarded as a form of compensation test. The technology would pass the compensation test if the wider economy could compensate the health care system for the loss of net health benefit (by making transfer T) but still provide net consumption benefits once the transfer is made:

$$-\Delta c_c \geq T \geq k\left[\frac{\Delta c_h}{k} - \Delta h\right], \quad £60,000 \geq T \geq £10,000$$

In this example the minimum compensation required by the health care system is £10,000 which is less than the consumption benefits ($-\Delta c_c$) so the technology should be approved. The opportunity costs of failing to internalise the external effects through transfers is the net consumption value (4) forgone by failing to approve the technology, which in this example is £30,000.

Of course implementing transfers is likely to impose additional costs because: i) there will be some transaction costs in identifying and making transfers; and ii) there may be efficiency losses in raising the resource from the private sector to make the transfer (e.g., through acceptable forms of taxation). The wider economy will now need to transfer T to the health care system but, in addition, bear the efficiency losses associated with raising the resources and making the transfer. However, transfers even with efficiency losses might be regarded as socially desirable over decisions based only on a health care system perspective. In this example above, substantial transactions costs (up to £30,000 per patient) could be worth while if the alternative is a decision based only on the health care system perspective.

Net consumption costs ($\Delta c_c > 0$)

If net health benefits are positive but the technology imposes consumption costs ($\Delta c_c > 0$) on the wider economy, the technology would still be acceptable if the consumption value of the net health benefits gained exceed the consumption costs. For example, if $\Delta h = 1$, $\Delta c_h = £10,000$ and $\Delta c_c = £5,000$ then:

$$v.\left[\Delta h - \frac{\Delta c_h}{k}\right] > \Delta c_c, \quad £60,000\left[1 - \frac{£10,000}{£20,000}\right] = £30,000 > £5,000$$

and the consumption value of the net health benefits exceeds the consumption costs. The overall net consumption value (4) is £25,000. It is possible to ask whether the health care system could make a transfer (T) to the wider economy to compensate for the costs imposed ($T \geq \Delta c_c$) while still regarding the technology as cost-effective once the transfer is made., i.e., so the net health benefits including the transfer are at least zero;

$$\Delta h - \frac{\Delta c_h}{k} - \frac{T}{k} \geq 0 \qquad (18)$$

Therefore, the maximum compensation the health care system could offer would be;

$$T \leq k.\Delta h - \Delta c_h, \quad T \leq £20,000 - £10,000 = £10,000$$

and the minimum compensation required by the wider economy would be $T \geq \Delta c_c = £5,000$; so, in this example, the health care system could in principle compensate the wider economy. However, it is very important to note that actually paying this compensation would reduce overall net consumption value because resources devoted to health are more valuable than that same resources devoted to consumption ($k < v$). In this example, if the minimum transfer of £5,000 was actually made the net consumption value would be:

$$v.\left[\Delta h - \frac{\Delta c_h}{k} - \frac{T}{k}\right] - \Delta c_c = £60,000\left[1 - \frac{£10,000}{£20,000} - \frac{£5,000}{£20,000}\right] - 0 = £15,000$$

rather than £25,000 by accepting the technology without making transfers. Therefore, transfers from a budget constrained health sector to the wider economy when $k < v$ would not be socially efficient. For this reason it is possible that the maximum compensation the health care system could offer may be less than the minimum required by the wider economy even when the overall net consumption value is positive and the technology should be accepted. Therefore, it is only transfers from the wider economy to the health care system that need to be considered and only when a technology does not appear cost-effective from a health care system perspective but also offers consumption benefits.

Non marginal changes

The examples above have considered only marginal changes. If the compensation was paid for each apparently marginal change there would be two advantages: i) the external effects would be internalised in decisions made from the perspective of the health care system; and ii) a sequence of marginal changes would not have longer run non marginal impacts because the health care system would be compensated for accepting technologies which did not appear cost-effective but did offer external benefits. However, transfers can also be used to compensate for the non marginal effect of single decisions. This would require knowledge of k^* (the cost-effectiveness threshold following a non marginal change, see Section 2.3).

The transfer required would need to provide sufficient resources to generate enough health elsewhere to just offset the net health benefits that will be forgone as a consequence of the non marginal impact of the technology, so the net health benefit including the health that can be produced from the transfer will be zero:

$$\Delta h - \frac{\Delta c_h}{k^*} + \frac{T}{k'} \geq 0$$

The minimum transfer required to compensate the health care system for a non marginal change would be:

$$T \geq k' \left[\frac{\Delta c_h}{k^*} - \Delta h \right]$$

Where k' represents the productivity of any transfer made. If the technology had no health effects ($\Delta h = 0$) then the transfer would need to be sufficient to reinstate all the treatments displaced by the technology to achieve the same level of health outcomes ($k' = k$). If the technology offered some health benefits ($\Delta h > 0$) then the transfer would not need to reinstate all displaced activities but only the most productive ones ($k' < k$). If the technology reduced health outcome ($\Delta h < 0$) then the transfer would have to be sufficient to reinstate all displaced activities and allow other less productive ones to be introduced ($k' > k$) to achieve the same overall health outcomes. The implications are that the transfers needed to compensate for a non marginal change will always be greater than a similar marginal change (because $k^* < k$) and will tend to be even greater when the technology does not offer health benefits (because $k' \geq k$).

Other budget constrained sectors

The same principles of transfers or compensation can be used to consider the impact of decisions in heath care on other budget constrained public sectors. For example, decisions in the health care sector may have an impact on educational outcomes and costs falling on a fixed education budget. If the objectives of collectively funded education can be summarised in a measure of educational outcome (e) and a threshold for the education sector (y) can be specified which represents the marginal productivity of the education budget, then the effect on education can be described as net educational benefit,

$$\Delta e - \frac{\Delta c_e}{y} > 0 \qquad (19)$$

The overall net consumption value of a technology which has impacts on the health and education sectors as well as the wider economy can be represented given a consumption value of educational outcome (z). The technology should be accepted if the impact on overall net consumption value across all sectors is positive:

$$v.\left[\Delta h - \frac{\Delta c_h}{k}\right] + z.\left[\Delta e - \frac{\Delta c_e}{y}\right] - \Delta c_c > 0 \qquad (20)$$

To simplify matters consider a situation where ($\Delta c_c = 0$) so the effects on the wider economy can be disregarded. Transfers between health and education would not need to be considered if the net health and net educational benefits were both negative (the technology should be rejected from both perspectives), or where they are both positive (the technology would be accepted from both perspectives). However, if there are negative net health benefits but positive net educational benefits, then the health sector will require compensation from education. The minimum transfer from education to health would provide just enough resources to offset the net health benefit forgone,

$$\Delta h - \frac{\Delta c_h}{k} + \frac{T}{k} \geq 0, \quad T \geq k\left[\frac{\Delta c_h}{k} - \Delta h\right] \qquad (21)$$

The maximum compensation that education sector could offer health would be the amount of resource that could be transferred without reducing net educational benefit,

$$\Delta e - \frac{\Delta c_e}{y} - \frac{T}{y} \geq 0, \quad T \leq y\left[\frac{\Delta c_e}{y} - \Delta e\right] \qquad (22)$$

Therefore, a transfer which would make the technology acceptable would be,

$$y\left[\frac{\Delta c_e}{y} - \Delta e\right] \geq T \geq k\left[\frac{\Delta c_h}{k} - \Delta h\right] \qquad (23)$$

Such a transfer will be possible if the positive net education benefits valued at y exceed the net health benefits valued at k , i.e.,

$$y\left[\frac{\Delta c_e}{y} - \Delta e\right] + k\left[\frac{\Delta c_h}{k} - \Delta h\right] > 0 \qquad (24)$$

Therefore, the value of transfers needed between sectors and whether such transfers are possible is straightforward – as long as the net benefit gained in one sector exceeds the net benefit lost in another (valued at their respective thresholds) then compensation is possible, transfers can be made and the technology should be approved. If k and y are regarded as the socially legitimate expression of the value society places on improvements in health and education delivered by collectively funded health care and education services, then this assessment of net benefit in each sector and the possibility of compensation is all that is required to establish whether the technology should be approved.

However, if some social welfare function is used as the basis of social choice then whether or not such transfers improve the overall welfare (the consumption value of outcomes across sectors) depends on the consumption value of health and educational outcomes (the value of v and z)

relative to the productivity of the health and education sectors (k and y). For example, if the education sector was regarded as relatively more 'underfunded' than health ($z/y > v/k$) then the same resources devoted to education would produce more valuable outcomes (in terms of consumption) than transferring those resources to the health sector. In these circumstances, making a transfer from education to health may not be desirable because it would reduce the overall consumption value of outcomes across both sectors. Equally, if health was regarded as relatively more 'underfunded' than education ($z/y < v/k$) then transfers from health to education should not be considered if it is possible to implement the technology without making transfers.

In general, the implications are that transfers between budget constrained sectors need only be considered in specific circumstances: i) the sector specific net benefits have different signs; ii) that the sum of the net benefits across sectors when valued at the marginal productivity of their budgets (their respective thresholds) is positive; and iii) if choice is to be based on some implied or explicit social welfare function transfers should only be considered from a sector which is judged to be less 'underfunded'. Of course, if making transfers between sectors is the only way to implement a beneficial technology with cross sectoral effects then transfers from a more to less 'underfunded' sector might still be worth while as the alternative of failing to approve the technology might provide even less overall net consumption value. It should be noted that if the respective thresholds are regarded as a revealed and legitimate expression of the value society places on sector specific outcomes (see Section 3), there is no question of whether each sector is 'underfunded' with respect to some alternate social welfare function. All that is required is an assessment of net benefit in each sector (valued at the respective threshold) to establish whether compensation could be paid and whether the technology should be approved. If implementing a policy of transfers associated with each technology is not regarded as feasible recording the net transfers or compensation required between different public sectors and the wider economy during a budgetary period could usefully inform subsequent reviews of public expenditure and its allocation.

3. Implications for policy

Although previous sections have formally considered in some detail the performance of a range of possible policies, it should be clear that the question of what is the appropriate perspective for decisions in health care made by a body like NICE is not simply a technical one but also poses fundamental questions of social value. These questions determine what wider effects should be measured, how they should be valued and whether these can be incorporated into decisions within the health sector in a formal and codified way. What perspective ought to be adopted and how it should be implemented turns on both the questions of value and the empirical questions of fact that follow. In considering such policy choices it is important to be aware of some of the possible wider and longer run implications.

3.1 Questions of value?

To formally take effects outside the health care sector into account when making decisions within the health sector some means to value health gained and forgone within the health sector relative to costs and benefits falling on the wider economy is necessarily required. The rates at which society is willing to trade social arguments including health and consumption is commonly described as a social welfare function. A key question is whether it is possible or desirable to specify such a description of all possible social states which will have implications for decisions across all sectors not just health. Even if there is generally no broad consensus or obvious social legitimacy for any particular specified or implied welfare function and the consumption value of health derived from it, the trade-offs will still need to be made. However, if a complete and legitimate specification of all social arguments is impossible, then attempts to formalise these trade-offs might be undesirable because the prescriptions may well conflict with other legitimate arguments and objectives of social policy, which may lead to undesirable and socially divisive changes to the health care system. In these circumstances a more deliberative approach might be regarded as more appropriate.

A formal prescription

The formal analysis in previous sections has taken a simple characterisation of social welfare which is implied by specifying a consumption value of health (v). Even if a particular consumption value of health could be agreed, the welfare function it presupposes is unlikely to capture everything of social value. Among other things it implies that health and consumption are the only arguments of social value, or that they are separable from other arguments (e.g., education, equity, social solidarity, etc) in some more complete description of social welfare.

As discussed earlier, welfare economics has traditionally taken a particular view of social welfare that rests entirely on individual preferences revealed through choices that individuals make especially in markets.[30] This has a number of implications for what effects count and should be measured and how they should be valued. In particular, market prices, including returns in the labour market, represent social values. If a market is distorted then observed markets prices can be adjusted (shadow priced) as if the market was competitive. In the absence of a direct market (e.g. health) to observe revealed preferences, values can be informed from implicit trade-offs individuals made in other indirect markets or preferences expressed in hypothetical choices (e.g., contingent valuation and discrete choice experiments). The implications are that i) the consumption value of health should be based on individual willingness to pay, i.e., individuals will have a different v depending on their income and other characteristics; ii) that any external effects should be valued at market (or shadow) prices including the value of time and labour market participation, i.e., returning patients to low wage labour is less socially valuable than to high wage labour; iii) all future related and unrelated costs should be accounted for; and iv) that any change in transfers (e.g., benefit payments) that occur simply cancel out because they represent no net social cost, except for any welfare loss due to taxation. It is implicitly accepted that the existing distribution of income is, if not 'optimal', then at least acceptable, possibly because it is viewed as the result of individual choices about investment in human capital and participation in the labour market.

This approach and the type of social welfare function it implies has often been modified by other social arguments. Most importantly by assigning some other societal value to some arguments such as health, e.g., using average rather than individual consumption values. Similarly average social

values of time and participation in the labour market rather than individual returns are also proposed. However, these *ad hoc* modifications imply some alternative 'optimal' distribution of income which, if made explicit and applied consistently, would require the adjustment of all values in all markets not just for health and other selected arguments. Also transfers between individuals (e.g., benefits payments as well as transfers from consumer to producer surplus) would no longer cancel.[46] In fact, if other means of achieving the implied optimal distribution of income are not possible then project selection itself can be used to move the distribution closer to what is regarded as optimal. In these circumstances additional weights would need to be specified and applied to all valuations.[46]

Some implications

The full formalisation of these trade-offs becomes very difficult because it poses fundamental questions about social value which have implications for all social choice and public policy, not simply health. The difficulty is identifying a particular welfare function and desired distribution of income which captures all social arguments and their interactions, and carries some broad consensus and social legitimacy. Even if such a welfare function could be identified a number of other problems remain:

i) Even if all arguments were separable in social preferences (e.g., the value of a change in health is independent of a change in education), these arguments tend not be separable in production. There are important relationships and feedbacks in the production of health, education and economic growth which means that evaluating policies as if health can be smoothly traded with education and consumptions is potentially misleading, i.e., the production possibilities surface is not smooth and may not allow simple predicable trade–offs even at the margin.[47]

ii) The fact that budgets must be regarded as fixed means that the opportunity costs of costs falling on the budget constraint must be fully accounted for. This requires estimates of an appropriate threshold (k) (see (4) Section 2.1). Analysis of policy C in Sections 2.2 and 2.3 demonstrates that it is not appropriate to apply traditional welfarist cost-benefit analysis with a broad perspective based in individual preference while ignoring the opportunity costs imposed by the budget constraint.

iii) Adopting a particular welfare function as a basis of social choice implies a particular interpretation of v and k. According to this interpretation, it is v alone which expresses social value. The budget constraint is simply a nuisance and the value of k it implies has no normative content whatsoever. Observing $k < v$ is an inefficiency which prevents the maximisation of (this particular definition of) social welfare by either allowing transfers or expanding the budget to the point where $k = v$.

iv) The informational requirements to fully account for marginal changes means that a 'second best' policy (see (12) in Section 2.2) which fully accounts for non marginal effects is unlikely to be possible. Therefore, a judgement would be required as to whether the non marginal effects are likely to be small relative to the external effects. If they are then decisions might be based on a first best rule (see (5)), where net consumption costs are taken into account as if the change was marginal. If the change (or series of changes) were judged to imply large non marginal changes for the health care system relative to the external effects, then any consumption benefits could be set aside but any consumption costs regarded as if they fall on the budget constraint (see Section 2.3).

v) There are other critical considerations, most importantly the net consumption costs or benefits which might be displaced by the new technology as well dynamic effects and other social considerations which are discussed in Section 3.3.

A deliberative approach

An alternative role for economic analysis is more modest, claiming to inform social decisions in health rather than to prescribe them - providing a useful starting point for deliberations, rather than making claims about social welfare or the optimality or otherwise of budget constraints. It is this role that CEA has tended to play in decisions about health technologies. Bodies such as NICE in the UK can be regarded as the agents of a socially legitimate higher authority which is unable to express an explicit and coherent social welfare function. In these circumstances the agent (NICE) cannot be asked to improve social welfare, since it cannot be specified. Rather, explicit resources are allocated by the

authority and are accompanied by a set of explicit and specific objectives (e.g., to improve health) for the agent to employ.
Health is implicitly traded with other aspects of social value, including consumption when a socially legitimate higher authority sets the budget for health care. The implications of this process (i.e., the shadow prices of the constraints imposed by the higher authority) are a partial social expression of some unknown underlying latent welfare function. i.e., an estimate of k can be taken to represent a legitimate but partial expression of how much society wishes to pay for improvements in health delivered by collectively funded health care.

If all costs fell on the health care budget and all benefits were in the form of health gains then all the agent (NICE) would require would be an estimate of k, Δh and Δc_h. Decisions based only on the perspective of the health care system would be complete and appropriate (see (1) in Section 2.1). However, once effects outside the health sector are acknowledged then some means to guide deliberations about the possible trade-offs is required. A general principle is to identify where the opportunity costs fall and then value them appropriately. Therefore, insofar as the external effects fall on individuals who are free to make choices about their consumption (including whether to invest in their health) some knowledge of how individuals value their consumption relative to health is needed In this context an estimate of v can be regarded simply as an expression of how much consumption individuals are willing to give up to improve their own health when making individual choices about their own consumption, rather than the primary expression of social welfare. External effects may, in part, also fall on other budget constrained sectors (see Section 2.4), or individual preferences may be modified by other social arguments. In which case a range of extra welfarist definitions of v that might not be based on preference at all could be used.

It should be clear that there is no reason to suppose that a social democratic process will deliver budget allocations which precisely match individual preferences, i.e., funding the NHS to the point where $k = v$. Aside from empirical observations there are good reasons why k is likely to be less than v, particularly if v is an average value across a highly skewed distribution of income. In particular: i) social decisions will take into consideration a range of different social arguments many of which are not separable from health and consumption and conflict with individual preferences, e.g., equity, social solidarity and cohesion; ii) collectively funded health care may be regarded as providing a socially acceptable provision while leaving individuals free to make their own consumption choices including whether to invest in improving their own health; iii) the acceptability and inefficiency of increasing socially acceptable forms of taxation to expand collectively funded health care to the point where $k = v$ may not be desirable even if other social arguments were not in play. Therefore, observing $k < v$ does not imply that budgets are not optimal and the health care system is underfunded, but simply that there is a difference between the implied social value of health provided by collectively funded health care and the amount of consumption that, on average, individuals are willing to give up to improve their own health.

Some implications
Although this approach is more modest and avoids the problem of specifying a particular welfare function, which carries some broad consensus and social legitimacy, the problem of trading net health benefits in the health care sector with consumption effects remains.

i) Economic analysis no longer provides a prescription for social choice but claims to inform a deliberative process by which decisions about health technologies are made. The question is what type of analysis and considerations might provide a useful guide to these deliberations and add to their transparency and accountability.
ii) Some information to inform plausible estimates of a consumption value of health would be needed to guide deliberations about the relative weight that might be attached to net consumptions costs (k/v). Some social value judgments about whether such values should be population averages would be required as well as scientific value judgments about which methods might provide the most appropriate estimates.
iii) This approach offers a very different interpretation of v and k. Rather than being the only expression of social welfare, v is an estimate of how much consumption individuals are willing to give up to improve their own health when making individual choices about their own consumption. Rather than being simply a nuisance, k is a partial expression of the value society places on health delivered by collectively funded health care.

iii) As above, the informational requirements to fully account for marginal changes means that a judgement would be required whether the non marginal effects on the health care system are likely to be small relative to the external effects. If they are, then some weight might be given to the external effects (see (5) in Section 2.1). However, if the change (or series of changes) were judged to have large non marginal effects on the health care system relative to the external effects, then any consumption benefits could be given less or even zero weight but any consumption costs could be given more weight.
iv) As previously noted, there are other considerations, most importantly the net consumption costs or benefits which might be displaced by the new technology as well dynamic effects and other social considerations which are discussed in Section 3.3.

3.2 Questions of fact

There are a series of empirical questions posed which ever view is taken of the role of economic analysis. However, the questions of value discussed above do determine what counts and should be measured, and who and how they should be valued. Estimating the expected incremental health benefits (Δh) and incremental costs (Δc_h) of a technology are already provided as part of NICE appraisal. However, considering a wider perspective and how that might be implemented poses a number of empirical questions and requires additional information which would need to be provided to decision makers.

Cost-effectiveness threshold (k)

Which ever view is taken, an estimate of k is required which should represent the health forgone on average across the NHS as additional costs displace other NHS activities, i.e., an estimate of the marginal productivity of the health care system. More recent attempts to estimate budgetary elasticities tend to support the lower threshold range use by NICE.[28] However, more robust estimates are possible and importantly some evidence of how k changes over time as budgets change but also as the productively of health care improves.

Is a change non marginal?

Estimating the impact of non marginal changes by providing precise estimates of k^* for each decision may not be feasible. However, some information about the scale of impact on the NHS budget of a single decision and information about the cumulative impact of decisions over time would inform judgements about whether changes can be safely regarded as marginal or should be treated as having non marginal impacts. It is possible that further development of the analysis of national Programme Budget data might also provide some guide to the potential impact of non marginal changes, i.e. how estimates of k change with overall budget impact.

Consumption value of health (v)

The type of valuation required depends critically on the questions of social value, i.e., individual valuations which will be a function of income and other characteristics, or some average valuation or valuation at some other 'optimal' distribution of income. In fact a value not based directly on individual preference is perfectly possible. Even if a more deliberative approach is adopted, some information to inform plausible estimates of how individuals value their consumption relative to their health would be useful. This would require some social value judgments about whether such values should be population averages as well as scientific value judgments about which methods might provide the most appropriate estimates.

Net consumption costs (Δc_c)

Net consumption costs can be thought of as having two elements: costs of care not borne by the NHS (Δc_c^c) and effects on the wider economy that are external to the patient and their family(Δc_c^e). The discussion of principles in earlier sections makes clear that consistency is required. Therefore, if external effects are to be more formally taken into account then both elements are equally important and relevant. It is difficult to conceive of a coherent principle that would allow a pick and mix approach to external effects, e.g., consideration of Δc_c^c but ignoring Δc_c^e would not be sustainable.

How estimates of Δc_c^c and Δc_c^e might be made are also discussed in Chapter 4. However, they are not provided in current NICE appraisals and the case studies in Chapter 4 show that robust estimates would need to be an integral part of the economic models submitted to NICE rather than an 'add on' to existing appraisals. There are further difficulties in establishing how these elements should be measured and valued. For example: i) should valuations be based on individual or population averages; ii) should productivity be measured using human capital or friction costs; iii) do measures of health related quality of life capture the financial (consumption) impact of ill health to the patient; iv) should consumption based on transfer payments (benefits) cancel; and v) what, if any, adjustment should be made to net wage rates for informal carer and leisure time? To some extent these and other questions of how to value external effects turn on judgements about social value described above. In addition, it should be recognised that the current approach taken by NICE of taking into account the impact on carer quality of life would need to be amended as it could lead to double counting. Either the costs falling on carers should be valued in terms of consumption (e.g. using some adjusted net wage rate) or valued using a QALY measure but not both.

It should also be apparent that taking more formal account of net consumption benefits would require additional analysis as part of NICE appraisal process. This would also require clear guidance on how such analysis ought to be done (what should be measured and how to value it). Of course, there will be a strong incentive for manufacturers to emphasise any potential consumption benefits and overestimate their value but underestimate or neglect any potential consumption costs. Therefore, any guidance would need to be sufficiently robust to make inappropriate claims detectable and the process of reviewing submissions sufficiently rigorous to detect false or biased claims. Both these aspects (additional analysis during appraisal and additional critical review) will necessarily add to the costs of appraisal. A judgement of whether the additional costs are likely to exceed any additional benefits of a more formal consideration is required.

Transfers between sectors
Transfers only need to be considered from the wider economy to the health care sector. If transfers between budget constrained sectors are regarded as a feasible way of internalising external effects then estimates of the net benefits in each sector are required. If some explicit or implied social welfare function is adopted as a basis of social choice then a judgement about the social value of sector specific outcomes relative to the marginal productivity of each sector (their relative underfunding) would also be required (see Section 2.4).

Although these requirements appear formidable, a number are already required within a health care system perspective. For example, the limited empirical basis for the current cost-effectiveness threshold range is widely acknowledged and research has recently been commissioned to provide more secure estimates, including, where possible, an assessment of the effects of non marginal budget impacts.[48] Other questions of measurement and valuation, such as a consumption value of health and the elements which make up net consumption costs, have been the subject of an extensive literature and (discussed further in Section 4.1). Although many of these questions have been considered in existing policy documents (including the Treasury Green Book[49]), the underlying questions of scientific and social value remain and are no less difficult for it. In summary, there are formidable scientific and social value judgements to be made but these can draw on an existing literature which has attempted to address these questions in different ways.

3.3 Other critical considerations

There are three other critical areas which require consideration: i) the need to make some assessment of net consumption benefits which might be displaced by the new technology; ii) the dynamic effects on prices and longer run investment incentives; and iii) potential conflicts with other social objectives.

Displaced consumption effects

All the analysis in previous chapters has focused on the additional net health and net consumption benefits offered by the technology under consideration by NICE. The fact that any additional health care costs will displace other health care activities resulting in forgone health elsewhere has been

discussed at length and represented by k in the expression for net health benefit (see (1) in Section 2.1). To simplify the notation in Chapter 2 it has been assumed that the health care activities which are displaced will have no net consumption costs or benefits associated with them, i.e., it is assumed Δc_c =0 for displaced health care. However, this is very unlikely to be true. The additional health care costs of new technologies will displace other health care activities, not only resulting in forgone health elsewhere, but also forgone consumption benefits to patients, carers and the wider economy, The overall effect on consumption of adopting the new technology would not be the Δc_c associated with it but the difference between the consumption effects of the new technology and those that are displaced. For example, if expansion of health visitor provision is displaced then potentially substantial net consumption benefits from improving long term health, educational and criminal justice outcomes for vulnerable children will be forgone. Therefore, it is not sufficient to observe net consumption benefits associated with a new technology but that these exceed the consumption benefits which may be forgone if the new technology is adopted and other activities are displaced elsewhere in the NHS. This can be represented more formally by amending (5) in Section 2.1:

$$\left[\Delta h - \frac{\Delta c_h}{k}\right] - \left[\frac{\Delta c_c}{v} + \frac{\Delta c_h}{j}\right] > 0 \qquad (25)$$

The first term represents the net health benefits falling on the health sector, which accounts for other health forgone due to Δc_h using the cost-effectiveness threshold, k. The second term represents the net consumption effects outside the health care system. It now includes $\Delta c_h / j$, which represents the net consumption costs displaced as Δc_h falls on the NHS budget and displaces other health care which also has $\Delta c_c \neq 0$. This formalisation requires some assessment of a threshold j which represents the NHS cost per net consumption cost forgone.

Any consideration of external effects can only reallocate existing NHS resources within a fixed budget. Therefore, any technology which is adopted as a consequence of considering external benefits must necessarily be at the expense of other NHS activities, i.e., extending the NICE perspective can be regarded as a 'zero sum game' over all NHS activities and technologies. However, it would change the mix and relative priority of particular technologies, tending to prioritise less effective technologies which offer greater net consumption benefits over more effective technologies which impose greater net consumption costs.

If the type of new technologies considered by NICE are in general able to demonstrate that their net consumption benefits (costs) are greater (lower) than those that are displaced, then the share of NHS resources devoted to these technologies will tend to increase (even if prices are unaffected - see dynamic effects below). This might be regarded as appropriate if a proper assessment of displaced external benefits has been made. However, if they tend to be underestimated or ignored then such reallocations would be wholly inappropriate, reducing health outcomes and consumption benefits to the wider economy. Equally, if new technologies tend to be associated with lower (higher) consumption benefits (costs) than existing NHS activities, then the share of NHS resources devoted to these types of technologies should properly fall.

Identifying precisely which activities are displaced at a local level in the NHS and estimating their associated cost-effectiveness from an NHS perspective is notoriously difficult.[50] It would be an even greater challenge to also try to estimate the associated wider costs and benefits. However, at a more aggregate level evidence suggests that the NHS is productive of health and that, on average across the NHS, a marginal reduction in budget (or equally imposing additional costs) is associated with reductions in health outcome.[51] There is also a range of evidence which suggests that improvements in health generally offer net consumption benefits to the wider economy.[52,53,54] Therefore, it is reasonable to suppose that, on average across the NHS, both health will be forgone when other health care is displaced and that this will also be associated with forgone net consumption benefits.

If, in general, net consumption benefits are associated with overall improvements in health, then those technologies which would already be regarded as cost-effective from an NHS perspective, and

therefore offer net health benefits to the NHS, will also tend to offer overall net consumption benefits as well. Equally, those technologies not currently regarded as cost-effective from an NHS perspective would, if approved, reduce health benefits across the NHS and tend to impose overall consumption costs. In these circumstances appropriate decisions could be made based only on an NHS perspective. Extending the NICE perspective would seem unnecessary in many circumstances as it should in principle make no difference to the guidance issued if it could be properly implemented. Extending the perspective for all technologies appraised by NICE would also impose additional costs on the appraisal process and introduce the possibility of a biased assessment if the wider consumption benefits which might be displaced are more difficult to identify but any wider benefits associated with a new technology are assiduously searched for, researched and presented.

However, an NHS perspective is only likely to be sufficient 'on average', and there will be exceptions: where the external benefits associated with the health gains are likely to be substantially greater or substantially less than the external benefits associated with health forgone elsewhere as other NHS activities are displaced. One approach to this problem would be to restrict consideration of wider effects to exceptional cases where an NHS perspective is more likely to be inadequate, i.e., where the external benefits are likely to be substantially greater or less than current NHS activities which may be displaced. A more selective approach would require explicit criteria for when an exceptional case could be made, possibly based on the nature of the technology (whether it affects quantity or quality of life), the type of disease (acute or chronic) and the type of patient population (age, employment status etc). It should be noted, however, that as well as identifying exceptions which are likely to offer overall net external benefits it will also be necessary to identify exceptions which are likely to impose overall net consumption costs.

It seems clear that whenever consideration is given to external effects this will need to be matched by a better understanding of the external effects of health care in general and those aspects of health care that are most likely to be displaced. Such assessment appear significantly more difficult in scope than estimating a cost-effectiveness threshold (the effect on health due to changes in expenditure)[28] based on national data reporting local variations in expenditure and outcomes. This is because, the effect on net consumption benefits will depend critically on which particular types of health care are invested or disinvested and which patient groups forgo health; a level of detail that is not currently available . Attempting to detect the wider economic effects of relatively small variations in local NHS expenditure based on aggregate economic data seems obviously hopeless. One possibility would be to match any proposed investment, where external effects are to be considered, with the specific disinvestment(s) that would be required. The external effects of both could then be estimated and compared. However, the difficulties remain but now become; how to establish criteria to identify suitable disinvestments which are 'marginal' with respect to health and wider effects? If the criteria do not identify 'marginal' activities, there will be a danger of acceptance when both the investment and disinvestment should be rejected or rejecting an investment when it should be accepted and the proposed disinvestment also retained.

Finally, it should be noted that although there are circumstances when consideration of wider effects may be unnecessary when considering allocation within a fixed budget (because the opportunity costs fall on health and therefore wider effects elsewhere), consideration of the wider economic benefits of improving health is always necessary and appropriate when considering how much resource should be devoted to health care (because the opportunity costs of an increase in the budget falls on consumption in the wider economy rather than on health).

Dynamic effects

Pricing incentives

Adopting a more formal consideration of external effects will change the incentives faced by manufacturers. The incentives at work, when making a submission and providing estimates of Δc_c, have already been discussed. However, it would also change incentives for the pricing of new technologies. Current NICE appraisal offers manufacturer the opportunity to price their technology to the point where the net health benefits to the health care system are zero. In doing so they are able to appropriate all the value of an innovation, at least during the period of patent protection.[55-57] If external effects are more formally considered using the type of decision rule (5) described in Section 2.1 then there would be an incentive to price technologies (increase Δc_h) to the point at which the

overall net health benefits, including the health equivalent of any net consumption benefits, will be zero:

$$\Delta h - \frac{\Delta c_h}{k} - \frac{\Delta c_c}{v} = 0$$

This has a number of important implications. At least during the period of patent protection any net consumption benefits offered to the wider economy will be appropriated by the manufacturer by extracting rent from the health care system through higher prices. In essence, the health care system becomes a means of making transfers between different sectors of the wider economy, i.e., from those sectors which receive the consumption benefits to the pharmaceutical or devices sector which owns the patent. However, if transfers are not made from the beneficiaries in the wider economy to compensate the health care system for paying for the benefits they still receive, then the non marginal long term consequences seem obvious. The incentives to price to appropriate all aspects of benefit turns what were external benefits ($-\Delta c_c / v$) into higher internal health care costs ($\Delta c_h - \Delta c_c / v$). Without either transfers from beneficiaries in the wider economy or compensating increases in the budget for health care through general taxation, an increasing proportion of the NHS budget will be devoted to payment of rent for benefits which fall outside health. Consequently a smaller proportion of the budget will be available to offer health care which improves health outcomes. Of course, if a technology is shown to impose overall net consumption costs on the wider economy then the incentive will be to either reduce price or accept that technology may not be approved. However, if on average those technologies appraised by NICE do indeed offer overall benefits to the wider economy (or equally if displaced consumption benefits are not properly assessed) then, on average, NHS costs will tend to rise.

Investment incentives

In the longer run, one would expect that these incentives will tend to influence investment decisions so that the type of technologies developed will be licensed in diseases and patient groups which are more likely to demonstrate overall net consumption benefits and command higher prices. Therefore, in the longer run, a formal consideration of external effects will tend to lead to technologies offering greater consumption benefits but which are fully appropriated during the period of patent protection, leading to higher NHS costs with more significant non marginal impacts on the NHS budget. Although the NHS and the wider economy will receive a share of these benefits following patient expiry, other newly patiently technologies will be launched, also commanding higher prices than would have otherwise been the case. Therefore, even in the long run NHS costs will be higher. In return more benefits will accrue to the wider economy. Whether or not this is regarded as desirable turns on whether the welfare function presupposed by specifying v is regarded as legitimate and complete. If it is, then prices will indeed align incentives for investment with this definition of social value and the change in the mix of technologies towards those that will tend to be less effective but offer greater wider benefits would be regarded as socially desirable. However, even in these circumstances the desirability of these dynamic effects depends on a number of consideration: i) unless either transfers are made or the NHS budget is continually increased to compensate for higher NHS costs (e.g., such that $k = v$) then welfare will not necessarily be improved; ii) although the relative rewards might be aligned, whether the increased share of value appropriated by the private sector is necessary and appropriate will depend on consideration of the public sector contribution to innovation and comparisons with returns to capital in other sectors of the economy. Of course, if the welfare function is incomplete and other social arguments are at play, or if displaced consumption benefits are not properly assessed then such dynamic effects might be regarded as wholly undesirable.

Social consensus considerations

Unless some broad consensus about the type of social welfare function which ought to inform social choice in health can be established, then formalising the trade-offs may lead to prescriptions which conflict with other legitimate objectives of social policy and widely held notions of justice and social solidarity. Indeed it may be perceived as conflicting with widely held notions of the underlying social principles of the NHS. Such conflict and potential divisiveness might make particularly unpopular decisions unsustainable, which in the longer run might undermine the credibility of NICE.

This is particularly the case when wider considerations will inevitably lead some technologies, which would have been accepted as cost-effective from the perspective of the health care system, to be

rejected. These will tend to be technologies in older populations or which offer life extension in chronic diseases where a return to productive activity is not possible. Such decisions might be very difficult to sustain if they rest on measurement and valuation of consumption benefits which are not widely accepted or if they conflict with other objectives of social policy or widely held social value judgements.

It is important to recognise that consideration of external effects would only reallocate existing NHS resources, not add to them. It would change the mix and relative priority of particular technologies; at the margin it would prioritise less effective technologies which offer net consumption benefits over more effective technologies which impose net consumption costs. Therefore, in the short run it would reduce the overall health gains from the NHS budget. If the welfare function adopted is complete then this should be regarded as wholly desirable. However, if it is not complete, i.e., there are other social objectives and arguments that are relevant but not included, then there will necessarily be conflict at some point. For example it will conflict with particular equity objectives in health care provision, tending to benefit economically active populations. In the longer run any net consumption benefit will be appropriated in high prices. This will tend to amplify both these effects: i) the change in investment incentives will tend to favour those technologies, diseases and populations where net consumption benefits can be demonstrated, adding to an adverse effect on certain equity objectives; and ii) a greater proportion of the NHS budget will be devoted to paying for the external benefits through higher prices, so the health gained from the NHS budget will be reduced even further.

A simple policy of health maximisation within existing budgets is obviously not, nor does it claim to be, a complete specification of social welfare. Any consideration of cost-effectiveness from a health care system perspective necessarily conflicts with other relevant social arguments. This might explain why NICE has not adopted a formal prescriptions but a deliberative approach, informed by instructions from the Secretary of State and the NICE social value judgments document[58]; a necessarily imperfect attempt to guide deliberation through the many and various conflicts with other social argument and objectives. In combination with the description of how considerations are undertaken during the appraisal process[59] and the opportunities for scrutiny, consultation and redress, provide a means of negotiating and balancing the often mutually conflicting issues that arise.

4. Illustrative examples

A conceptual framework, which examines how the cost-effectiveness of health care technologies might be assessed under a wider perspective, was presented in Chapter 2. This Chapter considers how costs and benefits external to the healthcare system could be measured and valued, and demonstrates how they might be incorporated into the type of appraisals and decisions made by NICE. To this end four case studies are presented each of which is based on previous cost-effectiveness evaluations originally conducted for the NICE appraisal process. In each case the original perspective of the analysis was restricted to the NHS. The reanalysis under a wider perspective is conducted based on reported results and other readily available data. The four case studies were selected to cover a range of circumstances which will determine whether a technology is likely to offer wider benefits or impose costs. These include: the type of the technology (e.g., primarily affects mortality or quality of life), the nature of the disease (e.g., acute or chronic) and the type of patient population (e.g., age, gender etc).

4.1 Valuing net consumption costs or benefits

There are well established methods for costing NHS resources for the purpose of the economic evaluation of healthcare technologies.[32] However, the measurement and valuation of costs which fall outside the health care sector is less well established, particularly within the UK where the emphasis has been restricted to the inclusion of NHS costs. In addition, how to measure and value different elements of external costs often turns on difficult to resolve questions of value and fact that were discussed in Sections 3.1 and 3.2. The external costs fall into two main areas: costs of care not borne by the NHS ($\Delta c_c^{\ c}$) and the indirect effects on the wider economy that are external to the patient and their family ($\Delta c_c^{\ e}$).

Costs of care not borne by the NHS
Costs of care not borne by the NHS include the costs of treatment which do not fall on the health care budget. The major non health care inputs into care outside of the healthcare sector are volunteer or carer time and patient time.[32] While the measurement of time itself is not controversial, there remain unresolved questions about how this time should be priced and hence valued in monetary terms. For volunteer or carer time it may be possible to use the market net wage rate, since in undistorted markets this should reveal an individual's marginal valuation of their time. However, this is likely to overestimate opportunity costs of most carer time. In addition, if carers gain some reward and reassurance from proving care themselves rather than employing others then market rates may over value the true opportunity costs. Similarly net wage might not represent the marginal value of a patient's leisure time as choice of working hours is often restricted, and proposed values range from zero to the overtime wage rate. Others suggest it should depend on what time is being sacrificed to reflect the value of the different types of activities that are forgone.[60] Much is unresolved, but for the purposes of the following case studies net wage rate is used. There are also other costs of care not borne by the NHS, for example transport costs and out of pocket costs which might include the costs of paid carer time. These are commonly valued at market prices.

Indirect external effects on the rest of the economy
The indirect external effect on the wider economy are effects external to patients and their carers but are valued by the rest of society (effects on patients and carers should have already been captured in measures of health related quality of life and $\Delta c_c^{\ c}$). For example, returning a patient to active participation in the labour market will, in many circumstances, add to production in the economy. This will be a net benefit to the rest of society if the value of the additional production exceeds the individual's additional consumption over their remaining life expectancy. How to value improvements in productivity due to reduced mortality or earlier return to participation in the labour market due to improved quality of life is a matter of debate.

There are two main approaches supported in the literature: the human capital approach and the friction cost method. The human capital approach suggests that any productivity gained or lost will extend over time and should be valued based on the gross earnings of employment. Gross wages are often recommended on the basis that the gross wage in an undistorted competitive market will be

equal to the social (market) value of the production (the marginal revenue product). However, some key assumptions are required: that the labour and associated product markets are competitive and undistorted; and that there is no involuntary unemployment due to structural problems in sectors of the economy. Therefore, the gross wage will overestimate the value of productivity (a shadow wage rate would be lower) if there is unemployment in the relevant sector or if there are distortions in labour and product markets.[15 46]

Others have proposed a friction cost approach to valuing productivity losses from ill health, which is based on the amount of production lost during the time it takes companies or organizations to restore the initial production levels.[61] The total friction cost will include the lost production (over a more limited time frame than human capital estimates) as well as the direct costs it must incur to restore these initial production levels (e.g., recruitment costs, training costs etc). The use of the friction cost approach results in much lower estimates of the value of production losses from ill health than those from the human capital approach. One study found that losses accounted for 2.1% of national income based on friction costs while the human capital approach estimated them at 18%.[62]

Although, returning a patient to the labour market will (in the absence of involuntary unemployment) add to production in the economy, some of this additional production will be consumed by the individual and, therefore, not benefit the rest of society (a different but important question is whether the consumption enjoyed by the individual is captured in estimates of health related quality of life or not - see below). Therefore, estimates of the external benefits to the rest of society must take individual productivity net of individual consumption or, if expressed as a net consumption cost (as in $\Delta c_c^{\ e}$), it is individual consumption net of individual production.[2] The literature on extra consumption as a result of improvements in health is limited. Clearly, increases in life expectancy result in additional consumption and some national aggregate data are available. However, whether there is any significant effect on consumption as a result of changes in the quality of life is unclear.

However, using only market valuations of productive activity will neglect the external value to the rest of society of the non market activities that improved health allows. Although such external non market effect exist, how to identify and value them while avoiding double counting is less clear. It should be evident that these considerations may also conflict with other social objectives and widely held social values. For example, if individual rather than population averages are used then technologies which reduce mortality in diseases which tend to be associated with low income or deprived communities will also tend to impose indirect external costs. Equally, a mortality reduction in diseases associated with economically active and more privileged groups will tend to offer indirect external benefits. Even if population averages are used, a mortality reduction in elderly populations will tend to impose costs whereas the same effect in younger and economically active populations will offer benefits. In addition to the assumptions of competitive and undistorted markets, simply using the gross wage to provide a social value of productive activity will tend to neglect the external value of other non marketed activities. For example it would assign no external social value to those not participating in the labour market who nevertheless may be engaged in socially valuable non market employment such as child care etc. The questions of social value and potential implications were more fully discussed in Chapter 3.

Financial impact on the patient

An important question is whether the consumption enjoyed by an individual as a consequence of improved length or quality of life is captured in estimates of health related quality of life (HRQL). If, when valuing health states, respondents take account of the impact that the health state would have on their ability to work and consume, then the financial effects on the patient will already be accounted for in estimates of QALYs gained. In these circumstances adding in the additional consumption enjoyed by the patients would double count these benefits. This is the position taken by the Washington panel[24] and others.[2, 43] It should be noted that NICE's preferred measure of HRQL, the EQ5D, includes in its description of health states the ability to perform 'usual social role' which will include participation in the labour market and it financial implications. Other measures of HRQL do not include social role specifically in their health sate descriptions so might be less likely to capture these effects in their health state valuations.

This is consistent with an alternate view, that the consumption or income effects are not currently captured within measures of HRQL,[63, 64] or at least they should not be. In these circumstances the

additional consumption enjoyed by the patient would need to be included as a benefit and set against any indirect external costs (consumption net of production). It should be clear that adding consumption as a benefit to the patient and also as a cost to the rest of society will cancel, leaving just the value of any production as a positive benefit. However, there are two additional considerations. In the UK there is a system of social insurance and employment rights which protects income and consumption against the most extreme consequences of ill health. Therefore, in responding to the EQ5D questionnaire one would expect UK respondents to take account of this. Secondly, if the consumption enjoyed by the patient is to be added as a benefit alongside improvement in HRQL, then any of the additional consumption which is based on transfer payments (e.g., benefit payments) must also be entered as a cost and cancel. This is because transfer payments allow consumption by the patient but at the expense of reduced consumption elsewhere. Of course, if there is a wish to take account of distributional issues then transfers will not cancel. However, this will pose the problem of specifying a desired distribution of income which will also have implications for all valuations not just benefit payments.

Estimating cost-effectiveness

As has been shown earlier in (5) in Section 2.1, the cost-effectiveness of a treatment can be expressed in terms of health when it has impact both inside and outside the health care system. As discussed above, the external net consumption costs (previously Δc_c in (5)) can be split into two main components, costs of care not borne by the NHS ($\Delta c_c^{\ c}$) and the effects on the wider economy that are external to the patient and their family (consumption less productivity, $\Delta c_c^{\ e} = \Delta consumption - \Delta productivity$). Therefore (5) can be extended to allow for these two components of net consumption cost,

$$\Delta h - \frac{\Delta c_h}{k} - \frac{(\Delta c_c^{\ c} + \Delta c_c^{\ e})}{v} \tag{26}$$

Similarly, the ICER decision rule expressed in (6) can also be extended,

$$\frac{\Delta c_h + \frac{k}{v}(\Delta c_c^{\ c} + \Delta c_c^{\ e})}{\Delta h} \tag{27}$$

However, it has also been suggested that QALYs may not capture the consumption or income benefits to patients. In this case excluding them as a benefit will underestimate the cost-effectiveness when there are consumption or income benefits from improve health. However, (26) can be easily extended to include additional consumption as an extra direct benefit of health care,

$$\Delta h + \frac{\Delta consumption}{v} - \frac{\Delta c_h}{k} - \frac{(\Delta c_c^{\ c} + \Delta c_c^{\ e})}{v} \tag{28}$$

Similarly, the ICER decision rule (27) can be extended to give:

$$\frac{\Delta c_h + \frac{k}{v}(\Delta c_c^{\ c} + \Delta c_c^{\ e} - \Delta consumption)}{\Delta h} \tag{29}$$

Therefore, there are two main ways to estimate cost-effectiveness from a societal perspective, each of which requires a judgement of whether the HRQL measure used does or does not capture consumption effects (QALY inc Con and QALY excl Con respectively in the tables in Section 4.2). These are demonstrated in the case studies reported below. It should be noted that the proportion of any additional consumption contributed by benefit payments and other transfers has not be estimated and entered as a cost. Therefore, estimates of cost-effectiveness based on the assumption that

HRQL does not capture income effects will tend to be overestimated if some additional consumption is based on transfers.

4.2 Case studies

Four case studies are presented below to illustrate how cost-effectiveness from a societal perspective can be estimated based on existing analyses and readily available data. They demonstrate how a wider perspective might be incorporated into the type of appraisals and decisions made by NICE and highlight what would be required during appraisal to provide sufficiently robust estimates. Each of the four case studies are based on previous cost-effectiveness evaluations, three of which were originally conducted for NICE technology appraisal. The reanalysis is based on the reported results and use of readily available additional evidence. Changes in productivity have been valued using the human capital approach and carer time has been valued at average net market wage rate. Each analysis reports estimates by type of patient group where separate estimate were available and estimates when the QALYs is judged to include or exclude consumption effects for the patient.

Laparoscopic assisted hysterectomy versus abdominal hysterectomy

The EVALUATE study was a study of two parallel, unblended, multicentre randomised trials that compared laparoscopic hysterectomy (LH) with abdominal hysterectomy (AH) and vaginal hysterectomy (VH).[65] The study was funded as part of the Health Technology Assessment Programme. Below the comparison of LH with AH is explored further.

The original study included an economic evaluation which was a cost-effectiveness analysis conducted over a 1 year time horizon. The costs were estimated from an NHS cost perspective. Compared with AH, LH had a higher mean cost per patient of £186 and a higher mean QALYs of 0.007. This resulted in an incremental cost per QALY gained of £26,507. Below a value of £20,000 per QALY, NICE generally will approve the introduction of technologies based solely on the cost-effectiveness estimate. Between a value of £20,000 per QALY and £30,000 per QALY a strong case relating to the degree of certainty in the estimate, the health related quality of life is inadequately captured or the innovative nature of the technology is required for NICE to recommend its use.[66] Current NICE guidance recommends the use of laparoscopic hysterectomy as an alternative to abdominal hysterectomy.[66]

The economic evaluation has been extended to take account of costs falling outside of the NHS. This was done using evidence from Table VII below and several assumptions. Firstly, it was assumed that the difference in the effects of the intervention are purely in terms of HRQoL and not mortality; therefore, patients will live for the same time and there are no differences in consumption between the two arms. Information on the number of days off work in both arms was available from the EVALUATE trial as well as the rate of employment of the patients, so these have been combined with evidence on wages to calculate the differential productivity costs between the two arms. It was assumed that the difference in the number of days to return to work would also be mirrored in the number of days the women would need to be cared for by a relative or friend. This information was combined with the average wage rate and the unemployment rate to calculate the difference in care costs between the two arms that does not fall upon the NHS.

Table VII. Evidence for laparoscopic assisted vs. abdominal hysterectomy

	Statistic	Source of Data
Age	41	Mean age at start of trial
Laparoscopic-assisted hysterectomy NHS cost	£1750.72	EVALUATE trial[65]
Abdominal hysterectomy NHS cost	£1519.64	EVALUATE trial[65]
Differential mean cost	£186	EVALUATE trial[65]
Laparoscopic-assisted hysterectomy QALYs	0.870	EVALUATE trial[65]
Abdominal hysterectomy QALYs	0.862	EVALUATE trial[65]
Differential mean QALYs	0.007	EVALUATE trial[65]
Average wage per day	£76.90	ASHE (for 40-49 year old women)[67]
Days lost from Laparoscopic arm	77.8	EVALUATE trial[65]
Days lost from work Abdominal arm	94.8	EVALUATE trial[65]
Differential days off work	17	EVALUATE trial[65]
Percentage of patients working	69.8%	EVALUATE trial[65]
Differential days of care	17	Assumes is equivalent to differential days of work
Average wage per day	£69.46	ASHE (for all working adults)[67] and unemployment rate

Using the data in the Table VII and the assumptions described previously, the following parameters to be used in the estimation of the cost-effectiveness of LH compared to AH have been calculated.

Table VIII. Parameters for cost-effectiveness analyses

Parameter	Value
Δh	0.007
Δc_h	£186
$\Delta c_c^{\ c}$	-£1180.88
$\Delta consumption$	£0
$\Delta productivity$	£912.50
$\Delta c_c^{\ e}$	-£912.50

As can be seen from Table VIII above, the care costs falling outside of the NHS have been estimated as £1180.88 less in the LH arm than in the AH arm. Similarly the productivity benefits have been estimated to be £912.50 more in the LH arm than the AH arm. Both of these are driven by the shorter recuperation time with LH (patients on average returned to work 17 days earlier). The above information can be combined using the formulae provided in the previous section to give estimates of the cost-effectiveness of LH compared to AH. Table IX below contains the net health benefit (NHB) and ICERs when QALYs are assumed to include consumption effects and also when they exclude them. These results have been calculated assuming the NICE threshold is £20,000 per QALY while the consumption value of health is £60,000. These are also compared to the estimates under the current NICE reference case.

Table IX. Results for laparoscopic vs abdominal hysterectomy

NHB (NICE)	NHB (QALY inc Con)	NHB (QALY excl Con)	ICER (NICE)	ICER (QALY inc Con)	ICER (QALY excl Con)
-0.0023	0.3259	0.3259	£26,571 per QALY	Dominates	Dominates

The savings outside of the NHS (in terms of both increased productivity and reduced non NHS care costs) result in the estimates for cost-effectiveness from a societal perspective appearing more favourable than under the NICE case. The cost savings are so large that they outweigh the positive costs in the NHS resulting in LH dominating AH (having increased health but cost savings). As noted previously, LH is recommended by NICE but the results provided in the table above show that the decision is marginal, with the NHB being negative when a threshold of £20,000 is used in the NICE case. However, taking a wider perspective makes LH more desirable as a treatment and would still be approved at much higher cost. It should be noted that the estimates of cost-effectiveness when

QALYs include consumption effects and when they exclude them are the same, as it has been assumed that there is no difference in mortality between the arms and therefore there is no difference in consumption between the arms.

The previous analysis has been based on the assumption that the introduction of LH would have only marginal effects on the NHS (i.e. that the extra costs would not result in a change of the threshold k). However, it is possible that the introduction of LH could result in very large costs falling on the NHS or, alternatively, that as part of a series of new technologies being introduced that the threshold could change. A previous study found that of the 72,629 hysterectomies performed in England and Wales in 1992-3 81% of them were abdominal hysterectomies.[68] If all of these were switched to laparoscopic hysterectomies, at an additional cost to the NHS of £186 per patients, then the total increased NHS cost per year would be £10.9 million.

It is also possible to calculate the amount that the threshold would have to change as a consequence of the non marginal impact (see Section 2.3 and a discussion of k and k^*) so that the technology would be on the margin of being cost-effective or not (i.e. at a k where NICE would indifferent between introducing the technology or not). In this case the NICE threshold would have to be reduced to £4,440 per QALY before LH no longer appeared to be a cost-effective use of resources from a societal perspective. This is very far from the current threshold and it would appear unlikely that the increase in NHS costs of £10.0 million per year could result in the threshold falling to this level, although in combination with the introduction of other new treatments which increase NHS costs there is a possibility the threshold could fall so low. However, more information on the NHS production function would be required to make any definitive statements on this.

Table X. Non marginal changes for laparoscopic vs abdominal hysterectomy

Parameter	Value	Source
Number of patients per year	58,830	Department of Health. Hospital episode statistics[68]
NHS budget impact	£10,942,285	
k for treatment to be on the margin of cost-effectiveness (QALY inc Con)	£4,440	
k for treatment to be on the margin of cost-effectiveness (QALY excl Con)	£4,440	

Zanavamir or oseltamivir compared to usual care for patients with flu

A recently conducted multiple technology appraisal for NICE considered the cost-effectiveness of antivirals (oseltvamir and zanamivir) for the treatment of naturally acquired influenza.[69]

The study, conducted with an NHS cost perspective, used a decision-analytic model to assess the cost-effectiveness of oseltvamir or zanamivir compared to standard care without antiviral treatment in 5 patient groups: (i) otherwise healthy children aged 1-14 years; (ii) 'at-risk' children aged 1-14 years; (iii) otherwise health adults aged 15-64 years; (iv) 'at-risk' adults aged 15-64 years; and (v) elderly aged 65 years or over. A patient is considered at risk if they have one or more of the following conditions: chronic respiratory disease, chronic heart disease, chronic renal diseases, chronic liver disease, chronic neurological conditions or diabetes mellitus. For the two healthy groups ((i) and (iii)) the comparison was between oseltvamir aand standard care, while for the other three groups the comparison was between zanamivir and standard care.

In the base case analysis for the report the ICERs for the 5 patient groups were as follows: (i) £7,322.22 per QALY, (ii) £1,733.33 per QALY, (iii) £5,534.62 per QALY, (iv) £2,280.00 per QALY, and (v) £562.26 per QALY. However, despite the low cost per QALY in all sub groups the NICE Appraisal Committee only recommended the use of the two antivirals in the at-risk populations and in subgroups of the elderly population (i.e. those who might be immunosuppressed). The Appraisal Committee felt that the base case ICERs in the healthy groups were unlikely to reflect the true ICERs in these groups.[70] However, for the purposes of this report, the base case will be taken as the basis for the extension of the analyses to a societal perspective.

The economic evaluation has been extended to take account of costs falling outside of the health care sector using data from Table XI and the following assumptions. The antivirals have short term HRQoL

effects, as a result of which patients are able to return to work earlier. Information on the difference in the time of returning to normal activities was available from the HTA report and was transformed into productivity benefits using information on average gross wages. In all populations except healthy children the antivirals were found to have small effects on mortality, therefore the treatments also have long term effects on consumption and productivity. Patients who did not die from flu were assumed to live to average life expectancy, therefore the difference in the productivity and consumption between the treatment alternatives could be calculated by multiplying the difference in probability of mortality by the discounted streams of wages and consumption for a patient, based on the average age in the subgroup and their life-expectancy. There were assumed to be no differences in care costs not falling upon the NHS in both alternatives.

Table XIa. Evidence for cost-effectiveness of Zanavamir and Oseltamivir

	Healthy children[1]	**At-risk children[2]**	**Healthy adults[1]**	**At-risk adults[2]**	**Elderly[2]**	**Source of data**
Incremental health effects (QALYs)	0.0018	0.0066	0.0026	0.0055	0.0159	Burch et al (2009)[69]
Incremental costs within NHS/PSS	£13.18	£11.44	£14.39	£12.54	£8.94	Burch et al (2009)[69]
Average age	4.75	4.75	53.66	53.66	86.76	Burch et al (2009)[69]
Average undiscounted life expectancy	75.02	75.02	28.01	28.01	5.29	Burch et al (2009)[69]
Absolute difference in probability of mortality between alternatives	0	0.00008795	0.00010129	0.00021505	0.003018	Burch et al (2009)[69]
Difference in time to return to normal activities	1.28	3.45	2.25	3.45	3.45	Burch et al (2009)[69]

[1] Incremental costs / health effects and ICER given for **oseltamivir vs usual care** (zanimivir dominated by oseltamivir)
[2] Incremental costs / health effects and ICER given for **zanamivir vs usual care** (oseltamivir extendedly dominated by zanamivir)

Table XIb. Other evidence for Zanavamir and Oseltamivir

Employment rate	73.6%	National Statistics[71]
Weekly consumption	£193.80	Family spending and family expenditure survey[72]
Gross wage per week- all employees by age		
16-17b	£78.80	ASHE[67]
18-21	£180.70	ASHE[67]
22-29	£359.90	ASHE[67]
30-39	£411.40	ASHE[67]
40-49	£384.50	ASHE[67]
50-59	£373.30	ASHE[67]
60+	£251.30	ASHE[67]

Using the data in Table XIa and b and the assumptions mentioned previously, the parameters to be used in the cost-effectiveness analyses were calculated. These are presented in Table XII below. For healthy children there were no external effects as they do not currently earn a wage and, therefore, short term effects can be disregarded. As the difference in mortality between the alternatives was

found to be zero there are also no long term external effects in terms of differences in productivity or consumption. At-risk children had no short run productivity effects as they were too young too work, but the differing mortality did lead to long term differences in the alternatives in terms of productivity and consumption. However, because of their age, the consumption effects outweighed the productivity effects resulting in positive external costs (i.e. they still have several years until they enter the workforce during which they are still consuming). The healthy and at-risk adults have large savings in external costs mainly as a result of large short term productivity gains because they are able to return to work early. The elderly population have large external costs as they were considered to be outside of the workforce and thus receive no productivity gains from reduced mortality and instead only increased consumption costs.

Table XII. Parameters for cost-effectiveness analyses

Parameter	Healthy children	At-risk children	Healthy adults	At-risk adults	Elderly
Δh	0.0018	0.0066	0.0026	0.0055	0.0159
Δc_h	£13.18	£11.44	£14.39	£12.54	£8.94
$\Delta c_c^{\ c}$	£0	£0	£0	£0	£0
$\Delta consumption$	£0	£24.22	£18.66	£39.62	£142.15
$\Delta productivity$ (short run)	£0	£0	£228.29	£350.04	£0
$\Delta productivity$ (long run)	£0	£21.88	£17.82	£37.84	£0
$\Delta productivity$ (overall)	£0	£21.88	£246.20	£387.87	£0
$\Delta c_c^{\ e}$	£0	£2.34	-£227.44	-£348.25	£142.15

Table XIII presents the cost-effectiveness results for the 5 patient groups in terms of NHB and ICERs for societal perspectives where QALYs include and exclude consumption effects, and for comparison also the NICE NHS perspective. As a result of there being no external effects for healthy children the three approaches all result in the same estimates of NHB and ICER. For all other groups there are positive consumption costs (as a result of the reduction in mortality from flu). Therefore, the results from the societal perspective, where QALYs are not considered to include consumption effects, are more cost-effective than those where QALYs are considered to include consumption effects. The large short term productivity benefits result in the societal perspective estimates for both the healthy and at risk adult populations being more favourable than the results under the NICE perspective, with the external cost savings being so large that the antivirals were found to dominate usual care (i.e. they have lower costs and positive health benefits). However, for the elderly group, the results suggest the treatment appeared less cost-effective with a societal approach when it is assumed that QALYs do include consumption effects because the increased consumption as a result of the reduction in mortality is not offset by any productivity effects. Similarly, for the at-risk children group the societal approach, with QALYs considered to include consumption effects, results in less favourable estimates of cost-effectiveness as their discounted increased lifetime consumption is not fully offset by their discounted increased lifetime productivity. However, in terms of ICERs, treatment with antivirals for all the patient populations would appear to be a cost-effective use of resources when a societal perspective is taken.

Table XIII. Results for Zanavamir and Oseltamivir

	NHB (NICE)	NHB(QALY inc Con)	NHB(QALY excl Con)	ICER (NICE)	ICER(QALY inc Con)	ICER(QALY excl Con)
Healthy children	0.001141	0.001141	0.001141	£7,322.22	£7,322.22	£7,322.22
At-risk children	0.006028	0.005989	0.006393	£1,733.33	£1,851.69	£628.25
Healthy adults	0.001881	0.005671	0.005982	£5,534.62	Dominates	Dominates
At-risk adults	0.004873	0.010677	0.011338	£2,280.00	Dominates	Dominates
Elderly	0.015453	0.013084	0.015453	£562.26	£3,542.34	£562.26

These analyses have assumed that any changes will only have marginal effects on the NHS budget. However, it is possible that this is not the case. In Table XIV below estimates of the NHS budget impact per year are presented. It should be noted that these represent the discounted impact on the NHS of the treatment over the patients' lifetimes given that they were treated in that year. These range from £3,014,727 for the treatment of healthy children to only £97,573 for the treatment of at-risk adults. The table also contains sensitivity analyses showing how low the NICE threshold would have to fall for the NHS to be indifferent about the use of antivirals (i.e. where if the threshold is above this k it is cost-effective and when it is below this k the treatment is not cost-effective). For example, for healthy children the NICE threshold would have to fall to £7,322.22 per QALY before the treatment is on the margin of being cost-effective or not. However, for the elderly, where QALYs do not capture consumption benefits, the threshold would have to fall as low as £562.26 per QALY for the treatment to be on the margin of being cost-effective or not.

Table XIV. Non marginal changes for zanavamir and oseltamivir

	Patient population per year	NHS budget impact per year	k for treatment to be on the margin of cost-effectiveness (QALY inc Con)	k for treatment to be on the margin of cost-effectiveness (QALY excl Con)
Healthy children	228,735	£3,014,727	£7,322.22	£7,322.22
At-risk children	20482	£234,314	£1,743.65	£1,642.57
Healthy adults	88,536	£1,274,033	£2,251.70	£2,147.18
At-risk adults	7781	£97,573	£1,109.32	£1,048.09
Elderly	11027	£98,581	£660.71	£562.26

Beta interferon for treatment of multiple sclerosis

In 2001 NICE commissioned a consortium based at the University of Sheffield to assess the cost-effectiveness of beta-interferon therapies for the treatment of multiple sclerosis.[73] They considered 6 possible treatment strategies as well as a no treatment strategy. Using a Markov model with an NHS perspective and a 20 year time horizon, none of the beta-interferon strategies were considered to be cost-effective with ICER estimates ranging from £40,685 per QALY to £97,690 per QALY when compared to no treatment. However, a complex risk sharing scheme was agreed to allow the provision of the treatments on the NHS.

The most cost-effective of the beta-interferon strategies (Beta Interferon 1-b 8MIU treating both secondary progressive MS and relapsing remitting MS) has been extended below to incorporate a societal perspective. The evidence in Table XV below was combined with various assumptions to allow the estimation of external effects. It has been assumed that the effects of the treatment are purely in terms of HRQoL and not in terms of mortality. Estimates for the annual cost of care falling outside the NHS and of productivity losses as a result of MS per patient were available from an external source.[74] It has been assumed that there is an equal reduction in carer cost and lost wages as a result of HRQoL improvements as there was a quality gain from treatment, where the quality gain has been estimated as the ratio of the QALY estimates for the two treatment alternatives. It has been assumed that these differences will be constant over the 20 year time horizon and, therefore, the difference in the discounted external care costs and productivity costs have been calculated over this period. As the effects of the treatment are assumed to be only in terms of HRQoL and not quantity of life there are also assumed to be no consumption differences between the alternatives.

Table XV. Evidence for estimation of cost-effectiveness of Beta Interferon

	Statistic	Source
Incremental QALYs	1.02	Tappenden et al[73]
Incremental NHS cost	£41,644	Tappenden et alt[73]
Proportional increase in quality of life	11.42%	Tappenden et al[73] and assumptions
Informal care costs per year	£4373	Kobelt et al[74]
Short term and long term sickness absence costs	£7695	Kobelt et al[74]

The information in Table XV and the assumptions above have been combined to estimate the parameters for the assessment of cost-effectiveness from a societal perspective. These are presented in Table XVI. As can be seen there are large savings in care costs not falling on the NHS

as a result of the improved HRQoL. Similarly, the increased productivity due to treatment and the absence of consumption effects has resulted in large external cost savings.

Table XVI. Parameters for cost-effectiveness analyses

Parameter	Value
Δh	1.02
Δc_h	£41,644
$\Delta c_c^{\ c}$	-£7347.44
$\Delta consumption$	£0
$\Delta productivity$	£12929.01
$\Delta c_c^{\ e}$	-£12929.01

Table XVII presents the NHBs and ICERs for the NICE perspective, the societal perspective where QALYs are assumed to include consumption effects and the societal perspective when QALYs are assumed to exclude consumption effects. As can be seen from the table, Beta Interferon treatment appears more cost-effective when a societal approach is taken as a result of the large cost-savings in the wider economy from increased productivity and reduced non NHS care costs.

Table XVII. Results for Beta Interferon

NHB (NICE)	NHB (QALY inc Con)	NHB (QALY excl Con)	ICER (NICE)	ICER (QALY inc Con)	ICER (QALY excl Con)
-1.0622	-0.72426	-0.72426	£40,827	£34,201	£34,201

As with the earlier case studies the previous analyses have assumed only marginal effects. However, Table XVIII contains information on the NHS budget impact. The table also shows that the NICE threshold would have to increase to £30,667 per QALY for the treatment to be on the margin of being a cost-effective use of resources. However, given the treatment involves large NHS costs, *ceteris paribus* it is more likely to reduce the cost-effectiveness threshold below £20,000 per QALY, and would certainly not result in the threshold increasing. Therefore, without either a large expansion in the NHS budget, or extensive cost savings elsewhere in the NHS, treatment with Beta Interferon for MS is still unlikely to be cost-effective. There are currently estimated to be around 2,600 newly diagnosed MS sufferers with relapsing/remitting MS in England and Wales each year; if all of these patients started Beta Interferon therapy the cost to the NHS over their life times would be £108.274 million.

Table XVIII. Non marginal changes for Beta Interferon

Patient population	NHS budget impact	k for treatment to be on the margin of cost-effectiveness (QALY inc Con)	k for treatment to be on the margin of cost-effectiveness (QALY excl Con)
2,600	£108,274,400	£30,667	£30,667

Statins for secondary prevention of coronary heart disease

A systematic review and economic evaluation of statins for the prevention of coronary events was commissioned by the HTA programme on behalf of NICE.[75] Below the results of this report with regards to secondary prevention of coronary heart disease (CHD) in men are considered. The report found ICER estimates of £10.24 per QALY, £10.02 per QALY and £10.54 per QALY in men with CHD aged 45 years, 55 years and 65 years respectively. These estimates are well below the NICE threshold of £20,000 per QALY and, therefore, the treatment of such patients with statins was recommended by NICE.[76]

These analyses have been extended with the use of the data in Table XIX and various assumptions to allow for a societal perspective. Information on life expectancy without treatment was not available from the report; however information was available in Johanneson et al (1997)[77] and a regression analysis has been used to extrapolate life expectancy by age. The incremental QALYs from the report were then converted into increased life expectancy by dividing through by the average quality of life score (as it has been assumed that the benefits of the treatment are purely through the impact on mortality). This was then added to the life expectancy without treatment to calculate life expectancy of

those receiving statin therapy. It has been assumed that the benefits of the treatment in terms of life expectancy are spread evenly over an average patient's lifetime. Therefore, the differing productivity and consumption between the two alternatives in any year is equal to the increase in life expectancy divided by the total life expectancy, and multiplied through by the relevant age specific productivity and consumption levels. These incremental productivity and consumption estimates for each year are then discounted appropriately and summed over the patient's lifetime to give estimates of incremental productivity and consumption as a result of statin therapy.

Table XIX. Evidence for statins in secondary prevention

	45 year old man	55 year old man	65 year old man	Source of data
Incremental QALYs	0.462	0.41	0.314	HTA report[75]
Incremental NHS costs	£4.73	£4.11	£3.31	HTA report[75]
Life expectancy without statins	24.09 years	18.57 years	13.06 years	Johannesson et al (1997)[77] plus assumptions
Increase in life expectancy as a result of taking statins	0.9325	0.7456	0.5286	HTA report plus assumptions
Consumption per week	£193.80			Family spending and family expenditure survey7
Income per week				
40-49	£706.30			
50-59	£648.00			
60+	£475.30			

Using the information available in Table XIX and the assumptions described previously the parameters for the estimation of cost-effectiveness were calculated. These are reported in Table XX below. As can be seen from the table the 45 year old men and 55 year old men have large productivity gains as a result of the reduced mortality, which outweigh the increased consumption which also results. In contrast, 65 year olds have been assumed to have left the workforce and therefore they have no productivity gains as a result of the mortality improvements and instead only the costs of increased consumption.

Table XX. Parameters for cost-effectiveness analyses

	45 year old men	55 year old men	65 year old men
Δh	0.462	0.41	0.314
Δc_h	£4.73	£4.11	£3.31
$\Delta c_c^{\ c}$	£0	£0	£0
$\Delta consumption$	£6,409.77	£5,583.55	£4,194.88
$\Delta productivity$	£18,066.65	£9,830.20	£0.00
$\Delta c_c^{\ e}$	-£11,656.88	-£4,246.65	£4,194.88

The parameters in Table XX have been combined to calculate the ICERs and NHBs associated with a societal perspective both assuming that QALYs include and exclude consumption effects. Table XXI also contains the results of the ICER and NHB for the current NICE perspective for comparison. As can be seen from the table the large productivity gains for 45 and 55 year olds result in statin therapy dominating the standard treatment arm when a societal perspective is considered (i.e. the treatment is both more effective and less costly). In contrast, the treatment of 65 year old men who gain no productivity from the reduced mortality but only the extra consumption appears less cost-effective with a societal approach. When it is assumed that QALYs do not take account of consumption effects the ICER for 65 year old men increases from £10.54 per QALY under the NICE approach to £4,463.70 per QALY under the societal perspective as a result of the large consumption costs caused by the mortality effects of statins.

Table XXI. Results for statins in secondary prevention

	NHB (NICE)	NHB(QALY inc Con)	NHB(QALY excl Con)	ICER (NICE)	ICER(QALY inc Con)	ICER(QALY excl Con)
45 year old men	0.461763	0.6560447	0.762874	£10.24	Dominates	Dominates
55 year old men	0.409795	0.480572	0.573631	£10.02	Dominates	Dominates
65 year old men	0.313835	0.2439199	0.313835	£10.54	£4,463.70	£10.54

As with the previous case studies our analyses have assumed that any changes are only marginal and therefore do not effect the cost-effectiveness threshold. However, this may not be the case. Table XXII presents the NHS budget impacts for treating the various age groups. It should be noted that these figures relate only to patients aged the exact age, and thus does not reflect the whole picture for the NHS (i.e. we haven't accounted for 46 year olds, 47 year olds etc). Table XXII also shows what the NICE threshold would have to be for the treatment to be on the margin of being cost-effective. If QALYs capture consumption benefits, then the NICE threshold would have to fall to £7.21 per QALY, £8.55 per QALY and £13.56 per QALY for 45, 55 and 65 year old men, respectively, for the treatments to be on the margin of cost-effectiveness (i.e. if the threshold was above this value the treatments would be cost-effective but if the threshold was below then the treatments would not be cost-effective). Similarly if QALYs do not capture consumption benefits then the NICE threshold would have to fall to £6.20 per QALY, £7.16 per QALY and £10.54 per QALY for 45, 55 and 65 year old men respectively for the treatments to be on the margin of cost-effectiveness. These are clearly very low values, and it would appear highly unlikely that the threshold would ever fall this low.

Table XXII. Non marginal changes for statins in secondary prevention

	Patient population per year[1]	NHS budget impact	k for treatment to be on the margin of cost-effectiveness (QALY inc Con)	k for treatment to be on the margin of cost-effectiveness (QALY excl Con)
45 year old men	1162.796	£5,500.03	£7.21	£6.20
55 year old men	2442.187	£10,037.39	£8.55	£7.16
65 year old men	2745.246	£9,086.76	£13.56	£10.54

1. Based on data from HTA report and population statistics- note this is specifically 45 year old men, we've excluded consideration of all 46 years olds etc so the figure is small.

4.3 Summary

Whether net consumption costs are positive or negative depends on the nature of the technology (i.e. whether it affects quantity or quality of life), the type of disease (acute or chronic) and the patient population (age, gender, employment status etc). As has been demonstrated in the case studies, age can have a significant effect on whether net consumption costs are positive or negative. For example, in the statins case study, those still participating in the workforce (45 and 55 year olds) have large net consumption benefits whilst older populations (65 year olds) have large net consumption costs.

The case studies have attempted to estimate net consumption costs by reanalysing published UK economic evaluations which were conducted to inform current NICE decision making. It should be noted that the estimates provided have required the use of aggregate external data and also some often strong assumptions which may not necessarily be accurate. For example, the estimates of changes in consumption are based on an estimate of the average consumption level for an individual in the UK (based on the average household consumption divided by the average household size). However, this level may differ by age, but this has not been taken into account in these examples. The estimates of productivity are based on gross wages, which may also underestimate the true productivity gains or losses, as they are based on the ASHE survey which only takes account of salaried staff and not those who are self employed or contract based who, on average, tend to have higher earnings. The only costs of care not borne by the NHS considered are carer costs which were valued at average net wage rates. This is likely to be an overestimate for two reasons: carers my not achieve average wage rates if participating in the labour market; and they may get other benefits from caring as discussed above. Clearly there are also other costs of care not borne by the NHS, for example travel costs. How such costs are linked to the quantity and quality of life in these case studies is unclear and no evidence was available for such costs to be estimated. Therefore, they have

been excluded from the above analyses. In addition no account was taken of consumption based on transfer or benefit payments.

Finally and most importantly, no attempt was made to assess the wider benefits that may have been displaced by these technologies, all of which impose additional costs on the NHS budget. Without an estimate of the consumption benefits that might be displaced elsewhere or comparing these proposed investments with specific disinvestments there will be a danger of 'doubly' false positive decisions, i.e., a technology may be approved when in fact the health forgone exceeds the health gained *and* the net consumption benefits forgone also exceed those gained. As discussed in Section 3.3, if consideration is given to external effects this must be matched by a better understanding of the external effects of health care in general and those aspects of health care that are most likely to be displaced

For these reasons the results of these case studies should only be regarded as indicative rather than robust and definitive estimates of the net consumption costs and benefits associated with these treatments. The analyses have also taken a very specific view on how to value these costs, e.g. the use of an average gross wage as the social value of productivity (i.e. a human capital approach instead of a friction cost approach), which is not the only approach that can be taken depending on the questions of value and fact outlined in Chapter 3.

To provide more robust estimates so that formal account could be taken of net consumption costs would require additional analyses as an integral part of the NICE appraisal process. Clear guidance on how this ought to be done would be required to allow a consistent approach across economic evaluations. The incentive will always be there for manufacturers to overestimate the value of consumption benefits and to underestimate, or neglect, any consumption costs. Therefore any amendments to the guide to the Methods of Appraisal would need to require analysis that was sufficiently robust to make inappropriate estimates detectable. The process of review of submissions would be need to be sufficiently rigorous to detect false or biased claims.

5. Summary of considerations

In most circumstances a technology will have effects outside the health sector including the direct costs of care that do not fall on the health care budget and the indirect external effects on the rest of the economy. The problem for policy is that, in the face of budgets set by a government, it is not clear how or whether a broader social perspective, which would include all these effects on all sectors should be implemented; particularly if transfers between sectors are not possible. It poses the question of how the trade offs between health, consumption and other social arguments, as well as the valuation of market and non market activities, ought to be done. Importantly, there is also the question of whether this should be formalised and codified or included in a more deliberative process.

The following key issues which have been examined in some detail in preceding sections need to be borne in mind when considering the possible policy responses to the problem of appropriate perspective. Key issues to consider include:

i) Whether a formalisation and prescription of the necessary trade offs based on a particular social welfare function is desirable and sustainable. This is particularly acute when there is no consensus on how to prescribe social choice, each alternate view generating potential conflicts with other agreed social objectives.
ii) The importance of accounting for the likely non marginal effects of individual decisions or a series of decisions.
iii) Whether transfers are regarded a feasible policy option. Even when they are not, whether some record of the net transfers or compensation required between sectors could usefully inform subsequent reviews of public expenditure and its allocation.
iv) The importance of making a proper assessment of any wider consumption benefits which maybe forgone as a consequence of the additional costs of a new technology displacing other health care activities.
v) The likely dynamic effects of more formally taking account of external consumption benefits, including incentives to appropriate external benefits though higher prices and the desirability of changes in the mix of technologies as a result of the investment incentives.
vi) Potential conflicts with other objectives of social policy as well as widely accepted principles of justice and social solidarity embodied in the NHS.
vii) The difficulty of resolving a series of questions of fact (see Section 3), including a range of unresolved questions about how best to measure and then value external effects.
viii) The additional costs that the assessments required would place on the NICE appraisal process if properly implemented with sufficiently robust methodological guidance.

Current NICE policy

NICE policy, following the 2008 revisions to the Methods Guide, restricted the perspective to the health care system (characterised as Policy A in section 2). In essence any wider effects outside the health care system are ignored, although any impact on the burden borne by carers is captured insofar as it affects measures of their HRQoL. Although, initially, this policy appeared difficult to sustain, in the light of further examination of the other considerations including the difficulty of robust measurement and the additional costs of appraisal, the potential biases associated with other feasible policies as well as their likely dynamic effects, it may well be a reasonable policy response to this problem.

This is particularly so once the difficulty of properly assessing the consumption benefits that may be forgone elsewhere is fully considered. If, in general, net consumption benefits are associated with overall improvements in health, then those technologies which would already be regarded as cost-effective from an NHS perspective and offer net health benefits to the NHS will also, in general, offer overall net consumption benefits as well. Equally, those technologies not currently regarded as cost-effective from and NHS perspective would, if approved, reduce health benefits across the NHS and tend to impose overall consumption costs. In these circumstances appropriate decisions can be made based only on an NHS perspective. Extending the NICE perspective would seem unnecessary in many circumstances as it should in principle make no difference to the guidance issued if it could be properly implemented. In addition, extending the perspective for all technologies appraised by NICE would impose additional costs on the appraisal process and introduce the possibility of a biased

assessment if the wider consumption benefits which might be forgone are more difficult to identify but any wider benefits associated with a new technology are assiduously searched for, researched and presented.

Although in general the health care system perspective is likely to be sufficient there will be exceptions: where the external benefits associated with the health gains are likely to be substantially greater or substantially less than the external benefits associated with health forgone elsewhere in the NHS. Current policy does allow consideration of limited external effects in exceptional circumstances, identified by the Department of Health before referral of the topic to NICE. If the criteria for exceptional circumstances were based on an assessment of whether the external benefits are likely to be substantially greater or substantially less than existing NHS activities this would signal to NICE when they might be considered as part of the Appraisal Committee's deliberations. It should be noted, however, that as well as identifying exceptions which are likely to offer overall net external benefits it will also be necessary to identify exceptions which are likely to impose overall net consumption costs.

Previous NICE policy

Prior to the 2008 Methods Guide NICE policy was more permissive. Although wider costs were not part of the reference case in the 2004 guidance, it was suggested that a non reference case analysis which included them would be taken into account in the deliberative process.

This could be interpreted as an implicit recognition of the more general approach to marginal changes (characterised as Policy D in 2.3 and first outlined in (5), Section 2.1) where wider effects are given some but not full weight (a weight equal to the ratio of the cost-effectiveness threshold to the consumption value of health). Under previous NICE policy, wider effects where 'taken into account' as an additional consideration, i.e., they were not given the same weight as costs falling on the NHS budget but neither were they given zero weight and ignored. The approach could be thought of as placing policy between the two extremes of attaching weights of zero or one to net consumption benefits or costs.

A more deliberative approach to this problem rather than adopting formal and explicit analytical rules might reflect the fact that that the cost impact on the NHS of these considerations will ultimately be non marginal and therefore might properly be disregarded in some circumstances (see Section 2.3). It might also reflect the fact that there is generally no broad consensus or obvious social legitimacy for any particular welfare function and the consumption value of health derived from it. Finally, even if a consumption value of health was regarded as acceptable, the welfare function it presupposes is unlikely to capture everything of social value. Again this general difficulty is reflected in the way NICE attempts to deal with a range of other social arguments described in its social value judgements document - that is, through deliberation.

However, a return to previous NICE policy would need to make the basis of any deliberation more explicit. For example, some further guidance on measurement and valuation of the various elements of wider effects would be needed. Some indication of the weight that might be attached (requiring some assessment of the consumption value of health) would be needed as well as a clear description of how this assessment might be modified by non marginal effects and potential conflicts with other objectives of social policy and social value judgements. The critical question of what wider benefits are likely to be forgone as a consequence of positive NICE guidance would also need to be addressed. Again it should be recognised that extending the perspective for all technologies appraised by NICE would impose additional costs on the appraisal process and introduce the possibility of a biased assessment if the consumption benefits which might be forgone are more difficult to identify. The problem may be more manageable if the consideration of wider effects was restricted to those exceptional cases where a health care system perspective is more likely to be inadequate, i.e., where the external benefits are likely to be substantially greater or less than current NHS activities which may be displaced and where the impact of approval is likely to be marginal. This more focused deliberative approach would require explicit criteria for when an exceptional case could be made, possibly based on the nature of the technology, the type of disease and the patient population.

Since, understandably, NICE is required to be increasingly transparent in its deliberations as well as its analysis, a return to previous guidance would require much more detail and pose the range of questions of fact and value (see Section 3) which are not easily resolved. If such deliberations are made more transparent and predictable then one would expect to see the type of dynamic effects on prices, NHS costs and the types of new technologies that were discussed in Section 3.3.

Other possible policy responses

The general approach to marginal changes (characterised as Policy D) which was outlined in Section 2.1 and applied in Sections 2.2 and 2.3 can be regarded as a formalisation of NICE guidance prior to 2008. A formal rather than deliberative approach could be adopted as NICE policy and would need to be included in the reference case for the methods of appraisal. However, this type of prescription would pose a number of difficulties and dangers. Such a formalisation would require a particular social welfare function to be specified with an associated estimate of the consumption value of health and explicit guidance on the measurement and valuation of the elements of external effects. Even if this was possible and desirable, three primary dangers remain: i) the repeated application of this policy will lead to non marginal changes, which, as demonstrated in Section 2.3, will introduce a positive bias in favour of new technologies; ii) the dynamic effects described in Section 3.3 will tend to increase prices and may not be desirable if either transfers or budget increases do not compensate for increased NHS costs; and iii) the difficulty of identifying the wider benefits which may be displaced will remain with the danger that any gains from new technologies will be more easily and readily identified than losses elsewhere.

It is possible to recognise the impact of the non marginal effects of a single decision or series of decisions by applying other decision rules when the non marginal effects are believed to be large relative to the external effects. In Section 2.3 the conditions under which a combination of polices might perform better than the general marginal decision rule were identified. For example, when a technology offers net consumption benefits but would lead to non marginal changes (more valuable health care would be displaced) it might be better to ignore the wider benefits if they are small relative to the likely non marginal effect (the negative bias from ignoring the benefits will tend to offset the positive bias from the non marginal effect). Equally, if the technology imposes wider costs then it might be better to treat these costs as if they fall on the NHS budget if the external effects are small relative to the non marginal effects. In this case the negative bias from treating the wider costs as if they fall on the NHS will tend to offset the positive bias from the non marginal effects.

This combination of policies would mitigate the dangers of non marginal impacts on the NHS. However, their implementation by NICE and the criteria for when each should be applied would require some knowledge of the likely impact of non marginal changes on the NHS, i.e., how the cost-effectiveness threshold changes with budget impact. Without some empirically based assessment, such a combination of policies may not be sustainable because NICE would be open to challenge if it decided to apply the more restrictive rules when non marginal effects where believed to be large relative external effects. Of course, this combination of polices does not overcome the other difficulties described above, including the explicit specification of a welfare function with potential conflicts with other social objectives, the likely dynamic effects, and the difficulty of adequately estimating displaced consumption benefits.

Simply ignoring the budget constraint was also examined as a possible policy option (characterised as Policy C). Although this represents the greater part of literature on evaluation outside health it fails to acknowledge or deal analytically with the salient feature of a collectively funded healthcare system like the NHS; namely, that the budget of such a system is properly allocated by a socially legitimate higher authority (e.g., the institutional arrangements of a social democratic process) and must be taken as fixed by decision making bodies such as NICE. The implication is that costs falling on the budget constraint displace health elsewhere, where as costs falling outside the budget on the wider economy displace private consumption.

For marginal changes, ignoring the budget constraint would be acceptable only if it could be established that the cost-effectiveness threshold was equal to the consumption value of health. However, there seems little reason to suppose that a social democratic process will deliver budget allocations which precisely match individual preferences. Aside from empirical observations there are good reasons why the threshold, which can be taken to represent a legitimate but partial expression

of how much society wishes to pay for improvements in health delivered by collectively funded health care, will differ from how much of their own consumption individuals are willing to give up to improve their own health. Even if a case could be made that this type of decision rule might be appropriate for a single marginal change, unless the non marginal impact of every decision was compensated by increases in the NHS budget it would quickly become inappropriate. Therefore, of all the policies examined, ignoring the fact of fixed NHS budgets has little to commend it.

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Appendix A.

The relative ranking of biases associated with 4 possible policies (A, B, C, and D) are summarised in Table VI. The ranking reported in the table assume that the difference between v and k is not trivial ($v > 2k$) and this difference is more significant than the impact of non marginal changes, i.e., $2 - \frac{k^*}{v} > \frac{k^*}{k}$. The ranking in parentheses requires in addition that the external effects are relatively large compared to health care costs and their non marginal impact on the budget. If these additional conditions do not hold the ranking in parentheses is reversed. Below the conditions relevant in each possible circumstance (represented by the ranking in each row of table IV) are outlined in more detail. Whether or not the technology is effective or not has no effect on the extent of bias. Therefore, the ranking of policies when $\Delta h > 0$ in the upper half of the table is identical to when $\Delta h < 0$ in the lower half.

Net consumption costs ($\Delta c_c > 0$)

Additional health care costs ($\Delta c_h > 0$ and $\Delta c_c > 0$)

D<A D is always less biased than A. No extra conditions are required because A always gives an additional positive bias when Δc_c is positive.

(D<B) D is less biased than B but only if an additional condition holds;
if $2\left(\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}\right) < \left|\frac{\Delta c_c}{v} - \frac{\Delta c_c}{k}\right|$

This condition will be more likely to hold when Δc_c is large relative to Δc_h and its non marginal impact (k^* similar to k). If the non marginal effects are large relative to the external costs then the ranking is reversed and B will be less biased than D.

D<C D is always less biased than C. No extra conditions are required because $v > k$.

(A<B) A is less biased than B but only if an additional condition holds;
if $2\left(\frac{\Delta c_h}{k^*} - \frac{\Delta c_h}{k}\right) < \frac{\Delta c_c}{k} - 2\frac{\Delta c_c}{v}$

The left hand side is always positive but since $v > 2k$ the right hand side is also positive. Therefore, this condition will be more likely to hold when Δc_c is large relative to Δc_h and its non marginal impact (k^* similar to k). If the non marginal effects are large relative to the external costs then the ranking is reversed and B will be less biased than A.

Summary (when $\Delta c_h > 0$ and $\Delta c_c > 0$)

If net consumption costs are expected to be large relative to positive health care costs and their non marginal impact, then policy D will offer the least bias because D<A, (D<B), D<C and (A<B). Since D always less biased than A, then when D<B, A must also be less biased than B by transitivity. However, if the positive health care costs and their non marginal impact are large relative to net consumption costs, then policy B would be least biased because D<A, (B<D), D<C and (B<A). Since D always less biased than A; when B<D, B must also be less biased than A by transitivity.

Reduced health care costs ($\Delta c_h < 0$ and $\Delta c_c > 0$)

D<A D is always less biased than A. No extra conditions are required because A always gives an additional positive bias when $\Delta c_c > 0$.

(D<B) D is less biased than B but only if an additional condition holds;

if $2\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right)<\left|\frac{\Delta c_c}{v}-\frac{\Delta c_c}{k}\right|$

This condition will be more likely to hold when Δc_c is large relative to Δc_h and its non marginal impact (k^* similar to k). If the non marginal effects are large relative to the external costs then the ranking is reversed and B will be less biased than D.

D<C D is less biased than C. No extra conditions are required because it is assumed that the difference between v and k is non trivial ($v > 2k$) and is more significant than the impact of non marginal changes, i.e.,

$$2-\frac{k^*}{v}>\frac{k^*}{k}$$

(A<B) A is less biased than B but only if an additional condition holds;

if $2\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right)<\frac{\Delta c_c}{k}-2\frac{\Delta c_c}{v}$

The left hand side is always positive but since $v > 2k$ the right hand side is also positive. Therefore, this condition will be more likely to hold when Δc_c is large relative to Δc_h and its non marginal impact (k^* similar to k). If the non marginal effects are large relative to the external costs then the ranking is reversed and B will be less biased than A.

Summary (when $\Delta c_h < 0$ and $\Delta c_c > 0$)

If net consumption costs are expected to be large relative to health care cost saving and their non marginal impact, then policy D will offer the least bias because D<A, (D<B), D<C and (A<B). Since D always less biased than A, when D<B, A must also be less biased than B by transitivity. However, if the health care cost savings and their non marginal impact are large relative to net consumption costs, then policy B would be least biased because D<A, (B<D), D<C and (B<A). Since D always less biased than A, when B<D, B must also be less biased than A by transitivity.

Net consumption benefits ($\Delta c_c < 0$)

Additional health care costs ($\Delta c_h > 0$ and $\Delta c_c < 0$)

(D<A) D is less biased than A but only if an additional condition holds;

if $2\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right)<\left|\frac{\Delta c_c}{v}\right|$

This condition will be more likely to hold when the absolute value of Δc_c is large relative to Δc_h and its non marginal impact (k^* similar to k). If the non marginal effects are large relative to the external benefits then the ranking is reversed and A will be less biased than D.

D<B D is always less biased than B. No extra conditions are required because B always gives an additional positive bias when Δc_c is positive because the common terms $\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right)$ are positive and equal so the additional bias of B also positive $\left(\frac{\Delta c_c}{v}-\frac{\Delta c_c}{k}\right)$.

D<C D is always less biased than C. No extra conditions are required because $v > k$.

A<B A is always less biased than B. No extra conditions are required because the common terms $\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right)$ cancel and the additional bias of B $\left(-\frac{\Delta c_c}{k}\right)$ is positive when $\Delta c_c < 0$.

Summary (when $\Delta c_h > 0$ and $\Delta c_c < 0$)

If net consumption benefits are expected to be large relative to the additional health care cost and their non marginal impact, then policy D will offer the least bias because (D<A), D<B, D<C and A<B. However, if positive health care costs and their non marginal impact are large relative to net consumption costs, then policy A would be least biased because (A<D), D<B, D<C and A<B. Since D always less biased than C then when A<D, A must also be less biased than C by transitivity.

Reduced health care costs ($\Delta c_h < 0$ and $\Delta c_c > 0$)

(D<A) D is less biased than A but only if an additional condition holds;

if $2\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right) < \left|\frac{\Delta c_c}{v}\right|$

This condition will be more likely to hold when the absolute value of Δc_c is large relative to Δc_h and its non marginal impact (k^* similar to k). If the non marginal effects are large relative to the external benefits then the ranking is reversed and A will be less biased than D.

D<B D is always less biased than B. No extra conditions are required because B always gives an additional positive bias when Δc_c is positive because the common terms $\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right)$ are positive and equal so the additional bias of B also positive $\left(\frac{\Delta c_c}{v}-\frac{\Delta c_c}{k}\right)$.

D<C D is less biased than C. No extra conditions are required because it is assumed that the difference between v and k is non trivial ($v > 2k$) and is more significant than the impact of non marginal changes, i.e.,

$$2-\frac{k^*}{v} > \frac{k^*}{k}$$

A<B A is always less biased than B. No extra conditions are required because the common terms $\left(\frac{\Delta c_h}{k^*}-\frac{\Delta c_h}{k}\right)$ cancel and the additional bias of B $\left(-\frac{\Delta c_c}{k}\right)$ is positive when $\Delta c_c < 0$.

Summary (when $\Delta c_h < 0$ and $\Delta c_c < 0$)

If net consumption benefits are expected to be large relative to the health care cost savings and their non marginal impact, then policy D will offer the least bias because (D<A), D<B, D<C and A<B. However, if health care costs savings and their non marginal impact are large relative to net consumption costs, then policy A would be least biased because (A<D), D<B, D<C and A<B. Since D always less biased than C then when A<D, A must also be less biased than C by transitivity.